

HOSPITAL MEDICATION ADMINISTRATION ERRORS

Their Simulation, Observation and Severity Assessment

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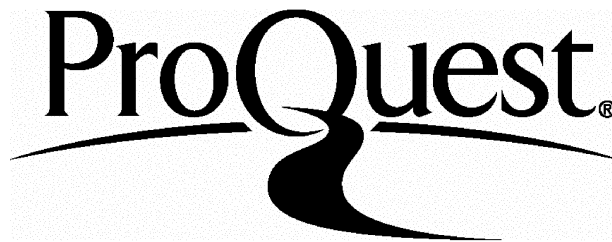
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Abstract

Background

Medication administration errors (MAEs) occur in about 5% of all doses given in UK hospitals. However, there are several reasons why existing methods for studying MAEs are inadequate. The aims of this research were to investigate the use of mathematical modelling to study MAEs and to develop a method for assessing MAE severity.

Methods

A discrete-event simulation model was developed to represent the hospital drug distribution system. The model was used to investigate the effects of different changes to the system on unavailability-related MAEs (U-MAEs), the most common type of MAE in UK hospitals.

A new method for assessing the severity of MAEs was developed; this was shown to be valid, reliable and practical for use in observation-based studies.

A patients' own drugs (PODs) system, one of the systems tested using the model, was introduced on two study wards; an observation-based method was used to identify MAEs before and after its introduction. The U-MAE rates identified were compared to those predicted by the model. Other types of MAE (O-MAEs) were studied and MAE severity assessed.

Results

The model's results suggested that the PODs system would reduce U-MAEs on each ward. However, this did not occur in practice. Four reasons for this finding were identified; three of these relate to assumptions made during model construction that hospital procedures would be followed. Had these four factors not existed, the real world U-MAE rates would have been very similar to those predicted by the model. There was no effect of the PODs system on the overall MAE rate or on MAE severity.

Conclusions

Mathematical modelling is a potentially useful approach to the study of U-MAEs, although the model developed needs some further refinements. The introduction of a PODS system had no effect on the incidence or severity of MAEs.

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Inside back cover: Fold-out diagram showing on-screen appearance of the entire simulation model.

Glossary

- **Analytical model** - A type of mathematical model that can be analysed using numerical methods such as algebra or calculus.
- **Continuous-time simulation model** - A type of simulation model in which a system is represented as changing continuously with respect to time.
- **Deterministic model** - A mathematical model in which there are no probability distributions and all parameters are considered to be without variability.
- **Discrete-event simulation model** - A type of simulation model in which it is assumed that events occur only at certain distinct times.
- **Input** - What goes into a process or a system. Inputs can include physical materials and information.
- **Mathematical model** - A simplified representation of a real world system, in which the relationships amongst the different parts of the system are described numerically.
- **Model** - A simplified representation of aspects of the real world.
- **Operational Research** - The discipline of using mathematical models to aid decision making.
- **Output** - The product of a process or system.
- **Probabilistic** - A situation that involves probability distributions.
- **Probability distribution** - If a variable can have a range of values, the probability distribution of that variable gives the probability of each value occurring.
- **Process** - An action or series of actions responsible for changing inputs into outputs.
- **Run-in time** - (also known as warm-up time) - The time taken for a simulation model to reach steady state or equilibrium. If steady-state conditions are desired then results should not be collected until after the run-in time had been exceeded.
- **Sensitivity analysis** - Investigation of the extent to which the results obtained from a model vary when the value of an input parameter is changed. Sensitivity

analysis is typically used where a range of possible values exist for an input, in order to determine the range of corresponding output.

- **Simulation** - The imitation of aspects of the behaviour of the real world, usually using a computer.
- **Stochastic model** - A mathematical model that includes one or more probability distributions and is therefore characterised by variability.
- **System** - A collection of inter-related inputs, processes and outputs.
- **Validation** - The process of ensuring that a model is an adequate representation of the system of interest for its intended purpose.
- **Verification** - The process of ensuring that a simulation model performs as intended and is free from programming errors.

Abbreviations

ANOVA	analysis of variance
ASHP	American Society of Hospital Pharmacists (now the American Society of Health-System Pharmacists)
CAPD	continuous ambulatory peritoneal dialysis
CI	confidence interval
CINAHL	Citation Index for Nursing and Allied Health Literature
DGH	district general hospital
EDMET	El Dorado Medication Error Tool
GSL	general sales list
HCFA	Health Care Financing Administration
ICC	intraclass correlation coefficient
JCAHO	The Joint Commission on Accreditation of Healthcare Organisations
LREC	Local Research and Ethics Committee
MAE	medication administration error
Mb	megabyte(s)
NHS	National Health Service
OE	opportunity(ies) for error
O-MAE	medication administration error related to causes other than unavailability
P	pharmacy medicine
PC	personal computer
PODs	patients' own drugs
POM	prescription only medicine
RAM	random access memory
SD	standard deviation
SE	standard error
U-MAE	unavailability-related medication administration error

Computer software

The following software packages were used:

- ABC Flowcharter version 4.0. Micrografx Inc, Richardson, Texas, USA.
- BestFit version 2.0d, Palisade Corporation, Newfield, New York, USA.
- Excel 97, Microsoft Corporation, Redmond, Washington, USA.
- Extend + Manufacturing versions 3.2 and 4.0.3a, ImagineThat! Inc, San Jose, California, USA.
- Ithink version 3.0.6, High Performance Systems Inc, Hanover, New Hampshire, USA.
- Simul8 version 3.0, Visual Thinking International Ltd, Glasgow, UK.
- Statistics Package for the Social Sciences version 7.5.1, SPSS Inc, Chicago, Illinois, USA.
- WordPerfect version 6.1, Corel Corporation, Ottawa, Canada.

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Preface

People generally undergo medical treatment in the hope that it will benefit their health. However, there is increasing awareness that patients may instead be harmed as a result of errors in medication use. It can be estimated that 1-2% of patients admitted to US hospitals are harmed as a result of medication errors (Leape *et al*, 1991; Bates *et al*, 1995; Leape *et al*, 1995; Andrews *et al*, 1997) and that each error that results in harm costs an additional \$5,000, excluding legal costs (Bates *et al*, 1997). Less is known about the impact of medication errors in the UK, but research suggests that we have no reason to be complacent.

Medication errors are of two main types: prescribing errors and administration errors. This thesis focuses on medication administration errors (MAEs) in hospital inpatients and considers their simulation, observation and severity assessment.

The thesis has five main parts, most of which consist of several chapters. The first part, Part A, provides an introduction to the whole thesis. MAEs are defined and previous studies discussed. The limitations of existing research are highlighted before explaining why a new approach to the study of MAEs is needed. Mathematical modelling is then proposed as a potential solution and the reasons for focusing on unavailability-related MAEs (U-MAEs) given.

Part B describes the construction of a mathematical model of the hospital drug distribution system, beginning in Chapter Two with an introduction to mathematical modelling and a discussion of its previous applications to pharmacy services. Chapter Three gives the rationale behind the mathematical modelling approach adopted and an account of preliminary modelling work. Chapter Four describes the data collection carried out and Chapter Five the development, verification and validation of the final simulation model. Chapter Six explains how this model was used to predict the effects of various changes to the hospital drug distribution system on U-MAEs.

Part C addresses MAE severity. Chapter Seven gives an account of previous approaches to severity assessment and explains why these are inadequate; in Chapter Eight, the development of a new method for assessing MAE severity is described.

Part D describes the trial of a patients' own drugs system, predicted by the model to reduce U-MAEs, on two hospital wards. Chapter Nine gives a detailed discussion of the relevant methodology. Chapter Ten then describes how an observation-based method was used to identify MAEs on each ward, and gives the results obtained. MAE severity is assessed using the new method developed and the U-MAE rates identified in practice are compared to those predicted by the model. The findings of this trial are then discussed in detail.

Part E draws together the main points of the thesis and discusses their implications, gives some suggestions for future work and summarises the conclusions.

Part A

Introduction

‘Where shall I begin, please your majesty?’ he asked.

‘Begin at the beginning’, the king said, gravely,

‘and go on till you come to the end: then stop’.

Lewis Carroll (1865)

Alice’s Adventures in Wonderland.

Chapter One: Medication administration errors

1.1 Introduction

A medication administration error (MAE) is any discrepancy between the medication prescribed for a patient and the medication administered (Allan and Barker, 1990); this includes the omission of doses that should have been given. MAEs, which can result from problems in the dispensing and supply of medication as well as in the administration process itself, have been recognised as a problem since the 1960's (Barker and McConnell, 1962; Crooks *et al*, 1965; Vere, 1965). Subsequent research has explored ways of identifying, assessing and preventing them. Until recently, the majority of this work originated in the USA; however, in the last five years a substantial body of research has also developed in the UK.

This chapter reviews published studies of medication administration errors in the USA, the UK and the rest of the world; the limitations of previous research will be highlighted and their implications for the present study discussed. MAE research has been closely linked to the development of hospital drug distribution systems, which will also be described where appropriate. This review is limited to studies of MAEs in hospitals; those in nursing or residential homes will not be considered. Some published studies include timing as a source of error and others do not, wrong time errors will therefore be excluded from all MAE rates quoted to increase their comparability.

1.2 Medication administration error studies in the USA

The first quantitative study of MAEs was published in the USA nearly 40 years ago (Barker and McConnell, 1962). As well as being the first study of the incidence of MAEs, this work was important as it led to observation becoming accepted as the best method for their detection. Barker and McConnell compared the numbers of MAEs detected using three different methods: hospital incident reports, anonymous reports and

observation. The observational method involved a researcher observing nurses preparing and administering medication, recording details of all doses administered, then comparing the observations with the prescribers' original medication orders to identify any discrepancies. The nurses were not told of the true reason for the observation. Although the other methods revealed few errors, the observational method revealed an MAE rate of 16.6%. This was calculated using as a denominator the total opportunities for error, defined as all doses given plus all doses omitted. It was concluded that observation is the best method for quantifying the numbers of errors that occur, that only about one in 1400 MAEs was reported on a hospital incident report form, and that the MAE rate was excessively high in the hospital studied.

At the time of Barker and McConnells' study, most US hospitals used either a total stock drug distribution system, in which bulk supplies of drugs were kept as stock on each ward, or an individual patient dispensing system, in which multiple dose supplies were dispensed for specific patients (Hynniman *et al*, 1970; Barker and Pearson, 1987). In both types of drug distribution system, doctors wrote medication orders on unformatted pages in the patients' medical notes, amongst orders for other therapies. Nurses were responsible for transcribing the doctors' medication orders onto medicines cards and for ordering drugs from the pharmacy department (Schwartau and Sturdavant, 1961; Barker and McConnell, 1962). The transcribed medicines cards were used by the nursing staff to determine the times at which doses of each drug were due; the administration of medication was documented in the nursing notes. Pharmacists rarely saw the original medication orders and served only a supply function.

Pilot studies of alternative drug distribution systems were described as early as 1961 (Schwartau and Sturdavant, 1961; Simpson and Carver, 1961) but it was not until after Barker published further studies of MAEs in the mid 1960's that major changes to US drug distribution systems occurred.

In the first of these, Barker and colleagues tested what became known as a unit dose dispensing system on one ward of the University of Arkansas Medical Centre (Barker and

Heller, 1963). The philosophy behind this system was that all responsibility for medication preparation should be taken by pharmacists rather than by nursing staff. The process of prescribing remained unaltered but dramatic changes were made to the processes of dispensing and administration; all ward stock drugs were removed and every dose dispensed by pharmacy staff just prior to its administration. Carbon copies of doctors' medication orders were sent by pneumatic tube to the pharmacy department, where details of each were recorded using punch cards. Every two hours, doses were dispensed and delivered to the wards in individual patient envelopes, using the punch cards to identify the doses due at each time. The punch cards were also used to print cumulative lists of active medication orders for each patient, which the nurses used as administration instructions. The nomenclature used on these lists was designed to be identical to that on the medication labels. The MAE rate was determined before and after the introduction of this system using an observation-based method, and was found to decrease from 14.4% to 1.8% (Barker *et al*, 1964). Following the success of this pilot study, the unit dose system was tested on a further eight wards in the same hospital. The MAE rate again decreased, this time from 13.0% to 1.9% (Barker, 1969).

Another study in a non-university hospital using a total stock system revealed an MAE rate of 6.7% (Barker *et al*, 1966). This is one of the most comprehensive observation-based MAE studies carried out to date; it includes analyses of inter-observer reliability and the effect of the observer on the nurses observed, as well as a detailed discussion of the methods used. An attempt was also made to assess the severity of the errors identified, but the method used has limitations which will be discussed in Chapter Seven.

Further observation-based studies confirmed that the unit dose system was associated with much lower error rates than traditional drug distribution systems. However in some cases, the comparisons were made across different wards or different hospitals (Hynniman *et al*, 1970; Means *et al*, 1975); the conclusions drawn from such study designs are weaker than those based on the comparison of different systems on the same wards. A comprehensive review of all observation-based MAE studies carried out between 1962 and 1987 has been published, from which a median MAE rate of 3.7% can

be calculated for hospitals using the unit dose system (Allan and Barker, 1990).

As the evidence in its favour grew, the unit dose system became advocated by the American Society of Hospital Pharmacists (now the American Society of Health-System Pharmacists) (anonymous, 1993) and was subsequently introduced in the majority of US hospitals. Other factors that contributed to this development were a shortage of nursing staff, perceived under-utilisation of pharmacy staff, problems with theft of medication from hospital wards and the requirement in a private health care system to charge individual patients for each dose administered (Buchanon, 1981; Barker and Pearson, 1987). Technological developments allowed the computerisation of pharmacy medication records and pharmaceutical companies responded to the needs of hospital pharmacists by supplying medication in unit dose packaging. A 1982 survey of US hospitals revealed that 61% used unit dose dispensing for 90% or more of their beds (Stolar, 1983); by 1992 this figure has risen to around 90% (Crawford and Myers, 1993). However, there are two key differences between today's unit dose systems and those initially evaluated. First, instead of supplying medication only two hours in advance, enough medication for twenty-four hours is usually supplied each day. It has been suggested that where this is the case, the system should not be considered a unit dose dispensing system because nurses have access to the whole day's medication for each patient (Barker and Pearson, 1987). Second, where a prescribed dose requires two or more dose units, the appropriate number of dose units are now supplied individually (Buchanon, 1981; Barker and Pearson, 1987). In the early unit dose systems, the correct number of dose units would have been supplied packaged together as one dose. Such differences may account for the MAE rates of up to 12.3% identified in more recent US studies (Barker *et al*, 1984a; Dean *et al*, 1995).

The main disadvantage of the unit dose system is that it is very labour-intensive (Barber *et al*, 1992). Pharmacy departments also need to have long opening hours; according to a 1996 survey, US inpatient pharmacy departments were open for a mean of 17.4 hours each weekday and 14.8 hours each weekend day (Reeder *et al*, 1997). In many hospitals, attempts have been made to reduce the heavy workload associated with unit dose

dispensing by introducing automated dispensing machines, based in the pharmacy department or in patient care areas (Barber *et al*, 1992; Lee *et al*, 1992; Wilson *et al*, 1993; Perini and Vermeulen, 1995; Goldberg and Clark, 1999). It was anticipated that such initiatives would also reduce MAEs, but this has not necessarily been the case. For example, the introduction of a bedside automated dispensing machine improved the timeliness of drug administration but had no significant effect on other types of error (Barker *et al*, 1984b). In another study, doses obtained from a ward-based automated dispensing machine were associated with a higher MAE rate (16.3%) than those dispensed in unit dose form by the pharmacy department or obtained from non-automated floor stock (5.4%) (Dean *et al*, 1995). Another study of a similar automated dispensing machine revealed an overall error rate of 6.5%; however this was reduced to 2.0% when it was interfaced with the pharmacy computer system and used to hold a wider range of medication (Borel and Rascati, 1995).

All of the studies cited so far have focused on the incidence of MAEs. Other US studies have examined the actual outcome of errors in medical treatment. However, as these studies generally include events other than MAEs, it can be difficult to elucidate the results that relate specifically to MAEs. For example, Leape *et al* (1991), in the Harvard Medical Practice Study, examined a random sample of medical records from 51 hospitals and identified 1133 patients (3.7% of admissions) with disabling injuries caused by hospital treatment. Careful reading of the paper suggests that 0.7% of the whole population suffered drug-related adverse events; this figure includes unavoidable adverse drug reactions as well as medication errors. The Adverse Drug Event Prevention Group (Bates *et al*, 1995; Leape *et al*, 1995) studied all 4031 adults admitted to a random sample of 11 medical and surgical units in two hospitals over a six month period. They detected adverse drug events (which included adverse drug reactions and medication errors) from self-reporting and daily review of drug charts. Overall, adverse drug events resulting from MAEs were identified in 0.8% of admissions. Such studies emphasise that MAEs can result in patient harm. Other US studies have assessed the outcome of MAEs identified on hospital incident reports (Demers and Moore, 1988; Hartwig *et al*, 1991; Bechtel *et al*, 1993; Schneider and Hartwig, 1994). However, the conclusions drawn

from such studies are limited by potential under-reporting of MAEs.

One of the reasons why medication errors have a relatively high profile in the USA is that hospitals are required to monitor medication error rates in order to satisfy their accreditation agencies. The Joint Commission on Accreditation of Healthcare Organisations (JCAHO) currently requires hospitals to monitor medication errors on an ongoing basis, but does not specify the data collection methods to be used or a maximum acceptable error rate (anonymous, 1993). The Health Care Financing Administration (HCFA), responsible for the accreditation of nursing homes and small hospitals, requires MAE rates to be measured periodically using an observational method (Feinberg, 1993). An error rate lower than 5% with no serious errors is deemed to be acceptable, although HCFA are considering reducing the maximum acceptable error rate to 2% (anonymous, 1998). However, it has been suggested that linking hospital accreditation to reported error rates only encourages under-reporting (van Leeuwen, 1994; anonymous, 1998) and JCAHO are now changing their emphasis from the error rates reported to the action taken following a serious error's occurrence (Leape *et al*, 1998).

In contrast, there are currently no specific requirements for UK hospitals to monitor medication errors and until recently they have received much less attention than in the USA.

1.3 Medication administration error studies in the UK

As in the USA, the development of hospital drug distribution systems in the UK has been closely linked to studies of MAEs; however until recently the studies carried out have been less rigorous than those in the USA.

The first UK studies of MAEs were published in the mid 1960's. At that time, the systems used for the prescription, supply and administration of drugs were very similar to those used in the USA prior to the introduction of unit dose dispensing. Doctors wrote medication orders in the patient's medical notes. These were then transcribed by nursing

staff onto medicines cards or lists. Nurses ordered drugs from the pharmacy department using either a requisition note or the original medication order, which was then absent from the ward while the medicines were being dispensed. Medication was administered using the medicines lists to determine when doses were due. The administration of medication was either not recorded or was documented only in the nursing notes. Sometimes these records were themselves used for subsequent administration (Vere, 1965; Baker, 1967). The use of medicines lists had been condemned as early as 1958, when it was suggested that drugs should instead be administered from the original medication order (Ministry of Health, 1958). However, this recommendation was not widely implemented until after the publication of several studies suggesting that the existing situation was dangerous.

One of these studies took place at The London Hospital, where Vere (1965) selected five long-stay patients receiving complex drug treatment, and for a three month period compared the ward sister's drug records with the original medication orders. Sisters' records were kept only for selected drugs; other medication was excluded. An error rate of 1.16% was reported; this figure was calculated using as a denominator the number of times a nurse had to read each medication order, regardless of whether or not a dose was due, and therefore cannot be compared with the results of other studies. The method used in this study can only provide information on discrepancies between the original medication order and the documented records; the medication actually administered was not considered. Nevertheless, the results were considered to mean that the existing system was associated with serious failings.

In another study, in Aberdeen, nurses' medicines lists were compared to the original medication orders (Crooks *et al*, 1965). The error rate determined is not quoted in the paper, but according to the authors, errors were "of sufficient frequency to be disturbing". As a result, a standardised prescription form was introduced that could also be used as a medicines list, thus avoiding transcription (Calder, 1965; Crooks *et al*, 1965). Different sections of the prescription form were reserved for regular, once only and parenteral drugs, with specific times of administration indicated for regularly administered

medication. A drug trolley was also introduced, containing a range of stock drugs to account for about 80% of the ward's needs. A ward pharmacist was responsible for checking the stock drugs, and for supplying non-stock drugs when required. However, the administration of medication was not documented. This deficiency was later rectified with the introduction of a separate recording sheet, cross-referenced with the prescription sheet. Discrepancies between the prescription and administration records were identified, but these fell from 10% of doses to 4% as staff gained familiarity with the new system (Calder and Barnett, 1967; Crooks *et al*, 1967).

In a further study at The London Hospital (Hill and Wigmore, 1967), twelve medical beds were continuously observed for seven days and the doses administered compared to the doctors' medication orders. An error occurred in 12% of all doses due. Modifications to the system were introduced one by one, and the error rate measured after each. The introduction of a combined prescription and recording document, a drug trolley and a ward pharmacist who inspected each drug chart daily reduced the error rate to 3.1%. This was the first observation-based study of MAEs published in the UK; unfortunately the precise methods and definitions used were not specified.

The Gillie report was produced in 1970 in response to these findings, advocating what was to become known as the ward pharmacy system (Department of Health and Social Services, 1970). In this document, the use of a combined prescription and administration record was recommended. It was suggested that the number of daily drug rounds should be standardised throughout each hospital, with medication administration carried out by two nurses. Each ward was to have both standard and ward-specific stock drugs, ordered by the sister when necessary. Finally, it was recommended that a pharmacist visited each ward regularly, to draw attention to any pharmaceutical problems and supply those drugs that were not ward stock.

The ward pharmacy system therefore developed in direct response to high MAE rates and by the early 1970's many UK hospitals were using this system (Baker, 1967; Ellis *et al*, 1972; Booth and Ellis, 1973; Watt *et al*, 1973). Trials of other drug distribution systems

have been carried out (Ellis *et al*, 1973; Miller, 1977; Calvert and Clarke, 1981; Prior, 1982; Jones and Ellis, 1983; Ganapathy, 1988), but these have had little impact on the almost universal acceptance of the ward pharmacy system. A survey carried out in 1992 revealed that inpatient drug charts were monitored on the ward in 93% of NHS hospitals, suggesting that ward pharmacy services were the norm throughout the UK (Cotter *et al*, 1994).

With a few exceptions (Miller, 1977; Bailie *et al*, 1981; Haslam, 1987), medication administration errors were ignored between 1970 and 1992. In 1992, however, the Boots Company decided to test Meditrol, an automated ward-based unit dose dispensing machine, at the Luton and Dunstable hospital (anonymous, 1992). Since little was known about the performance of the existing ward pharmacy system, this was first evaluated in detail (Ridge, 1998). This evaluation included an observation-based study of MAEs on two medical wards, two surgical wards and two care-of-the-elderly wards; the overall MAE rate was found to be 3.5% (Ridge *et al*, 1995). Although it was believed that the introduction of Meditrol would reduce errors, a repeat evaluation showed that the MAE rate remained unchanged (Jenkins, 1997). As well as demonstrating that the introduction of an automated dispensing system would not necessarily reduce MAEs in a UK hospital, this research was significant for two other reasons. First, the paper by Ridge *et al* (1995) was the first major UK study of MAEs to be published since the 1960's. Second, it was the first UK MAE study to use a method based on Barker and McConnells' (1962) observation-based technique. However, one major change to Barker and McConnells' method was necessary in order to adapt it for use in a UK hospital; this involved an ethical issue that had not arisen in the USA. In UK hospitals, an observer can see the original medication order, in the form of the drug chart, at the time of administration; as a result he or she is usually aware of MAEs as they occur. The observers in Ridge *et al*'s (1995) study therefore intervened in a standardised, discreet manner to correct errors before the doses concerned were administered. In contrast, in US hospitals the researcher does not know which doses were in error until his or her observations are retrospectively reconciled with the original medication orders in the patients' medical notes; the researcher is therefore not in a position to intervene.

The error rate identified in Ridge *et al*'s study was comparable to those previously reported for the US unit dose system (Allan and Barker, 1990). However given potential differences in definitions, observers and methods, in 1993 it was decided to carry out a comparative study of MAEs in an American and a British hospital. This would permit a more realistic comparison of the ward pharmacy system and the unit dose system, using identical definitions and observers, matched wards and comparable methods. In this study, two observers, one from each country, each observed drug administration in a UK hospital and a US hospital (Dean *et al*, 1995). In the UK hospital, two medical wards, two surgical wards and two care-of-the-elderly wards were studied to allow comparison with Ridge *et al*'s study. In this hospital, the observers intervened wherever it was possible to prevent an erroneous dose of medication from reaching the patient; interventions were made for 32% of all MAEs identified. Any educational effect of the interventions was considered insignificant as the same nurse was rarely observed administering the same medication to the same patient. Two combined medical-surgical nursing units were studied in the US hospital, which operated a unit dose system. Intravenous and controlled drugs were excluded from the analysis as these were not observed in the UK hospital. Errors were classified according to type and their most likely cause. The MAE rate in the UK hospital was found to be 3.0%, which was comparable to that identified in Ridge *et al*'s study (1995). In the US hospital the error rate was 6.9%, which is higher than the rates identified in earlier studies of unit dose systems (Allan and Barker, 1990). As well as the error rates being different, the errors identified in each system were of different types and causes. For example, the UK ward pharmacy system was associated mainly with omissions, the US unit dose system with unordered dose and incorrect dose errors. The main causes of MAEs in the ward pharmacy system were nurse selection errors and unavailability of non-stock medication. In the unit dose system the main causes were nurse selection errors and errors in the entry of doctors' medication orders into the pharmacy computer system.

Since these studies were published, interest in medication administration errors has increased in the UK. One factor likely to have contributed to this phenomenon was the loss of Crown immunity in 1991, following the 1990 National Health Service and

Community Care Act. This means that individual hospitals can now be sued for negligence. Many hospitals have set up anonymous reporting schemes (Cavell, 1995), with the aim of encouraging error reporting so that specific problems can be identified. A regular column in the journal *Pharmacy in Practice* (Cousins and Upton, 1994) describes medication error case reports and suggests methods for reducing errors. Further observation-based studies of MAEs have also been carried out; these are summarised in table 1.1. In the majority of these, the most common type of MAE has been the omission of doses due to unavailability of medication; this type of MAE has a reported incidence of between 1.2 and 2.4%. Other UK studies have focused on specific stages of the drug distribution system such as dispensing (Spencer and Smith, 1993), the omission of doses (Pare, 1995) and the timing of drug administration (Craig *et al*, 1994; Lewis *et al*, 1996).

The studies cited in table 1.1 differ from one another in many ways. For example, only Ho *et al* (1997) state that weekends were included. These authors found that on the care-of-the-elderly ward studied, the MAE rate was significantly lower at the weekend (4.0%) than on weekdays (6.4%). Only half of the studies cited (Dean *et al*, 1995; Ridge *et al*, 1995; Ho *et al*, 1997; Jenkins, 1997; Taxis, 1997) specify that evening and early morning drug rounds were included. Nixon and Dhillon (1996) studied paediatrics; the other studies were carried out on adult wards. Only Ridge *et al* (1995), Nixon and Dhillon (1996) and Jenkins (1997) included intravenous drugs, although a separate study has examined medication errors associated with intravenous medication in more detail (Hartley and Dhillon, 1998). There are also some differences in the criteria used for a medication administration error. For example, Gethins (1996) included as errors some doses intentionally omitted by the nurse according to his or her clinical judgement; others exclude these as opportunities for error. Analysis of the original research report for Nixon and Dhillon's paper reveals that errors prevented by a second nurse were included in the figures quoted (Nixon, 1995): such incidents are not considered MAEs by other researchers.

Study	Hospital type	Opportunities for error	Overall MAE rate* (95% CI) [†]	MAEs due to unavailability (95% CI) [†]
Ridge <i>et al</i> , 1995	650 bed, former DGH [‡]	3312	3.5% (2.9 to 4.1%)	1.5% (1.1 to 1.9%)
Dean <i>et al</i> , 1995	900 bed, teaching	2756	3.0% (2.4 to 3.7%)	1.2% (0.8 to 1.6%)
Gethins, 1996 [#]	former DGH [‡]	2000	3.2% (2.4 to 4.0%)	1.5% (1.0 to 2.0%)
Nixon and Dhillon, 1996	not stated	912	5.0% (3.6 to 6.4%)	Not stated
Ho <i>et al</i> , 1997	600 bed, former DGH [‡]	2170	5.5% (4.5 to 6.4%)	1.4% (0.9 to 1.9%)
Cavell and Hughes, 1997	computerised prescribing	1295	5.5% (4.3 to 6.7%)	Not stated
Cavell and Hughes, 1997	manual prescribing	1206	5.7% (4.4 to 7.0%)	Not stated
Ogden <i>et al</i> , 1997	Scottish general hospital	2973	5.5% (5.1 to 5.9%)	1.4% (1.0 to 1.8%)
Taxis, 1997	850 bed, teaching	842	8.0% (6.2 to 9.8%)	2.4% (1.4 to 3.4%)
Jenkins, 1997	650 bed, former DGH [‡] with ADM [◇]	5021	3.6% (3.1 to 4.1%)	1.4% (1.1 to 1.7%)

Table 1.1 Observation-based studies of medication administration errors (MAEs) carried out in the UK since 1990.

* There are many differences in the criteria used for opportunities for error and MAEs; different studies' results are not necessarily comparable.

[†] CI: confidence interval. Where these are not quoted in the papers cited, they were calculated as described by Gardner and Altman (1989).

[‡] DGH: District General Hospital.

[#] Typographical errors in this paper make the results difficult to interpret.

[◇] ADM: automated dispensing machine.

Most of these studies were descriptive rather than experimental, and two studies that compared different drug distribution systems did so in different hospitals; their conclusions are therefore limited by potential differences between the hospitals studied (Dean *et al*, 1995; Cavell and Hughes, 1997). The only UK authors to have assessed the severity of the MAEs identified are Nixon and Dhillon (1996) and Ogden *et al* (1997); unfortunately the validity of the methods used was not considered.

1.4 Medication administration error studies worldwide

MAEs have been studied in countries other than the USA and UK, but the methods and definitions used show even greater variation. For example, several studies of MAEs have been carried out in Australian hospitals. Two of these were based on retrospective chart review (Brooks *et al*, 1977; Kruse *et al*, 1992) and another on tablet counts (Corak and Hartigan, 1978); both of these methods are likely to underestimate the numbers of errors that occur. In addition, the results of these studies are difficult to interpret as the methods used are not given in detail. A small observation-based study in an Australian hospital using the ward pharmacy system revealed an MAE rate of 7.4% after the exclusion of documentation errors (Rippe and Hurley, 1988). A larger study using observation was also carried out in a ward using a total stock system (Stewart *et al*, 1991). The medication error rate was 11.2% excluding documentation errors and those corrected by the patient, a finding that was used to justify the introduction of a ward pharmacy service.

Unfortunately there are no published reports of the MAE rate following the implementation of a ward pharmacy service. Another observation-based study suggested that the MAE rate was lower for medication stored in bedside medicines cabinets than for medication kept in individual patient compartments outside each ward bay (Camac *et al*, 1996). However, the sample sizes in this study were very small and the difference is not statistically significant when timing errors are excluded.

More recently, an observation-based study in an Australian hospital using a total stock system revealed MAE rates of 6.5% and 9.3% on a medical and a surgical ward respectively, excluding documentation errors (McNally *et al*, 1997). Failure-mode and

effects analysis was then used to design a new drug distribution system, in which five-day supplies of medication were dispensed for each patient and stored in locked bedside drawers. The medication error rates identified for the new system were 1.2% and 2.4% on the medical and surgical wards respectively, representing statistically significant reductions.

The only major outcome-based study to be carried out outside of the USA also took place in Australia; this large multi-centre study suggested that 0.8% of hospital inpatients suffer harm as a result of medication errors (Wilson *et al*, 1995). However, this figure includes prescribing errors as well as MAEs .

Many Canadian hospitals now use unit dose systems similar to those used in the USA. One large study examined the effects of converting from traditional drug distribution systems to unit dose dispensing in four Canadian hospitals (Schnell, 1976). MAE rates were determined using an observation-based method, and were found to increase in one hospital, decrease in two and show no significant change in another. The author suggests that the main reason for the increased error rate in the first hospital was that the pharmacy department was closed at weekends and thus discontinuation orders could not be processed; many MAEs involving the administration of unprescribed doses therefore occurred each weekend. An attempt was also made to assess the severity of the errors identified, but the method used was not assessed in terms of validity or reliability. Another Canadian study on two paediatric wards demonstrated that the MAE rate decreased from 10.3% to 2.9% following conversion to a unit dose system (O'Brodovich and Rappaport, 1991). However the methods used may have underestimated the error rates as the observer's notes were initially compared with the pharmacy medication profiles rather than with the original medication orders; original medication orders were examined only where discrepancies were identified between the pharmacy profile and the medication administered.

In Continental Europe, most hospitals use total stock drug distribution systems similar to those used in the UK and USA prior to the introduction of ward pharmacy and unit dose

systems. Nurses generally transcribe doctors' medication orders onto medicines cards and order the drugs required from the pharmacy department. In many hospitals, nurses prepare all scheduled doses during the night, separating them into those scheduled for the subsequent morning, afternoon, evening and night (Arndt, 1994). However, pharmacists in many European hospitals are now considering changing to unit dose dispensing, partly because this is believed to be one of the best ways of involving pharmacists in drug therapy (Arce, 1996). A survey carried out in 1995 suggested that about 6.5% of European hospitals were operating unit dose systems, the remainder using ward stock-based systems (Delaney, 1996). However the response rates were very low for some of the countries included and the results suggest that the term 'unit dose' was interpreted in different ways by different respondents. For example, Delaney's survey indicates that 6.7% of Swedish hospitals use the unit dose system, while other authors suggest that two thirds of all hospitals in Sweden use this system (Branstad *et al*, 1994). Discussions with European colleagues suggest that some consider the supply of ward stock in blister packaging to be unit dose dispensing; results from such surveys should therefore be interpreted with caution.

A small number of studies have examined the MAE rates associated with total stock systems in European hospitals. A German study, for example, quotes an error rate of 4.6% (Meyer *et al*, 1983); however these authors included errors in the recording of verbal orders and other documentation errors as well as administration errors. Other studies have since been carried out in German hospitals (Decker and Meyer, 1988; Reißer and Großharth, 1996; Mehrrens and Carstens, 1997; Zieglmeier *et al*, 1998), but only one has used the standard observation-based method (Taxis, 1997). In this study, it was found that MAEs were less common in a hospital using a unit dose system than in a hospital using a total stock system; however the wards studied may not have been comparable.

In a large French study (Jaubert de Beaujeu and Bureau, 1988), medication errors were examined in a hospital that used a ward stock system, a non-computerised unit dose system and a computerised unit dose system. Actual administration to patients was not observed; instead the medication in the unit dose trolley or nurses' medicine trays was

examined. MAE rates of 0.6% (floor stock), 0.9% (manual unit dose) and 0.2% (computerised unit dose) were identified. The relatively low error rates may be due to the observations being made at an intermediate stage of the drug distribution system rather than at administration, or as the authors suggest, because nurses were told of the study's purpose. A further limitation of this study is that the wards studied were of very different specialities.

A study carried out in Spain examined MAEs associated with a unit dose system, but the precise methods used were not specified (Lacasa *et al*, 1994); a more recent observation-based study in the same hospital found that MAE rates were lower for medication orders that prescribers entered directly into the computer system (2.9%) than for those written on paper and faxed to the pharmacy department (6.2%) (Lacasa *et al*, 1998). However, this study included as MAEs patients' refusal of medication, wrong time errors and nurses' failure to inform patients about the medication administered. The results of quantitative MAE studies have also been published in Turkey (Cesur, 1988) and Malaysia (Hassan, 1993), but the definitions and methods used are difficult to elucidate.

It is noteworthy that the MAE rates reported in European hospitals using total stock drug distribution systems are considerably lower than those identified in the USA and UK prior to the introduction of unit dose and ward pharmacy systems. Potential reasons for this include differences in study methods and definitions, as well as differences in the drug distribution systems used.

1.5 Discussion and implications for the present study

Studies of MAEs have been an important driving force behind the development of today's hospital drug distribution systems. However, there are several reasons why further changes to drug distribution systems are inevitable. Patterns of hospital utilisation are changing and financial pressures are increasing, while developments in computerisation, automation and electronic data transfer are creating more options than previously thought possible. Concern over medication errors continues to increase, particularly in view of

today's increasingly litigious society, and the complexity of drug treatment, thought to have been one of the main factors contributing to MAEs in the 1960's (Vere, 1965) continues to grow.

As a result of these factors, pharmacists worldwide are considering changing the ways in which medication is supplied to hospital inpatients. In the UK, it has been suggested that the ward pharmacy system is no longer the optimum model for the provision of pharmacy services, and that alternatives should be sought (Cousins and Luscombe, 1996; Farrar *et al*, 1998). Rigorous studies of MAEs will be needed if such changes are to be properly evaluated. Unfortunately, existing approaches to studying MAEs have five major limitations.

First, the only way of assessing the MAE rate associated with a particular drug distribution system is to test it in practice. However, this approach is time-consuming, expensive, and may put patients at risk if a new drug distribution system results in increased error rates. Studies suggest that it is difficult to predict the effects on MAEs of different changes to the hospital drug distribution system; in some cases, changes predicted to reduce MAEs have done so (Barker and Heller, 1963; Barker *et al*, 1964; Hill and Wigmore, 1967; McNally *et al*, 1997), while in others they have not (Barker *et al*, 1984a; Barker *et al*, 1984b; Cavell and Hughes, 1997; Jenkins, 1997).

Second, most studies are descriptive rather than experimental, and those that are experimental generally have weak study designs. It is almost impossible to carry out randomised controlled trials of different drug distribution systems, but results from other types of study can be difficult to interpret due to potential differences in staff, systems of work or patient populations. These problems could be alleviated to some extent using a health technology assessment approach, which involves assessing the full implications of a particular technology in a structured manner (Littenberg, 1992; Jennett, 1993; Jenkins, 1997). However, this would be both expensive and time consuming.

Third, studies usually have low generalisability. The labour-intensive nature of data

collection means that most studies are carried out on a small number of wards in one hospital, over relatively short time periods. It is not known whether the results obtained apply to other wards or other hospitals and it cannot be assumed that a system that reduces errors in one environment will do so in another.

Fourth, close inspection of published studies reveals that MAEs can be defined in many different ways and that many studies contain insufficient detail to determine the precise methods and definitions used. It is therefore almost impossible to compare the results of different studies and very difficult to draw conclusions about the relative benefits of drug distribution systems that have been studied by different authors.

Finally, little is known about the outcome of MAEs. Most studies focus on the incidence of errors in the administration process rather than on the resulting patient outcome. This is mainly because outcome-based studies are more difficult to carry out. Yet counting only the numbers of errors that occur in different systems may obscure important differences in their clinical significance. In a small number of observation-based studies, attempts have been made to assess the severity of the errors identified (Barker *et al*, 1966; Schnell, 1976). However the methods used have not been assessed in terms of reliability or validity.

The first four limitations suggest that an alternative approach to the study of MAEs is required. Ideally, this approach would allow the MAE rates associated with different drug distribution systems to be predicted without having to implement and evaluate each one in practice. Systems that are unlikely to be useful could therefore be sifted out and only the most promising ones subjected to more extensive testing.

A technique that could potentially be used to solve this problem is that of mathematical modelling. A mathematical model is a simplified representation of a real world system, in which the relationships amongst different parts of the system are described numerically. Mathematical modelling can often be used to predict the effects of different options without the expense and disruption of experimenting with real world processes,

and this approach is now considered a powerful tool for making decisions about effective and efficient health care (Shahani, 1996). In the present case, a mathematical model could be used to investigate the effects on MAEs of different changes to the hospital drug distribution system, without having to implement each change in practice. Such an approach would also alleviate problems with experimental design, generalisability and MAE definitions, as drug distribution systems could be tested under many different conditions.

It was therefore decided to investigate a mathematical modelling approach to designing drug distribution systems that reduce MAEs. For the purposes of this study, it was decided to focus on unavailability-related MAEs (U-MAEs) as these are the most common type of MAE in UK hospitals. In view of the fifth limitation highlighted, it was concluded that methods for assessing MAE severity should also be explored. The remainder of this thesis is devoted to the investigation of these issues. The two key aims were:

1. To investigate whether mathematical modelling could be used to study the effects on U-MAEs of changing the hospital drug distribution system.
2. To develop a method for assessing MAE severity.

The next part of the thesis describes the construction of a mathematical model of the hospital drug distribution system, beginning in Chapter Two with an introduction to mathematical modelling.

Part B

The construction of a mathematical model of the hospital drug distribution system

‘Just as with a piece of Impressionist art, which may represent reality in a fashion quite differently from, say, a photograph or an engraving, various types of models may also portray the same slice of reality quite differently’.

John Casti (1997)

*Would-be worlds: How simulation is
changing the frontiers of science.*

Chapter Two: Introduction to mathematical modelling

2.1 Introduction

This part of the thesis describes how mathematical modelling was used to explore the effects of different changes to the hospital drug distribution system on unavailability-related medication administration errors (U-MAEs). This chapter gives an introduction to mathematical modelling, Chapter Three then describes the preliminary stages of model development and Chapter Four the data collection carried out. Chapter Five gives an account of model construction, verification and validation; Chapter Six describes the experiments conducted using the model and discusses the results obtained.

This chapter begins with a discussion of some different types of model and their advantages and disadvantages. The stages of a typical mathematical modelling study will then be described, before giving an account of previous applications of mathematical modelling to pharmacy services.

2.2 Models

A model is a simplified representation of the real world. To test the effects of changing a real world system it may be possible to experiment with the actual system or a model of the system. Each of these approaches has advantages and disadvantages.

Experimenting with real world systems has obvious advantages. The results are relevant and practical issues can be dealt with at an early stage. However, experimenting with some real world processes can be expensive, disruptive or even dangerous. For example, testing different drug distribution systems in a hospital would be likely to cause considerable inconvenience to patients and staff; it could also be dangerous if some of the changes increased medication error rates. If many different options exist, it may be necessary to implement many changes before a satisfactory option is identified and

reversing the effects of each unsuccessful change could be difficult. Furthermore, if the process involves rare events such as serious medication errors, it may take a long time before the relative risks and benefits of each change become apparent. In other cases the problem may involve a facility that does not yet exist, in which case experimenting with real world processes would be impossible.

Modelling eliminates many of these potential problems. Multiple options can be tested without disruption or risk to the people involved. Long time-scales can be compressed into much shorter periods and very short time periods expanded to allow more detailed analysis. Modelling allows parameters to be controlled precisely; alternatives can therefore be tested under identical experimental conditions, a situation that is rarely possible in real world research. Because modelling requires an analysis of the interactions and relationships involved, it can also lead to a greater understanding of the system being studied.

The main disadvantage of modelling is that the validity of the model as a representation of the real world can be difficult to ascertain; users must be convinced that a model's validity is acceptable before its conclusions can be put into practice.

Models can take many different forms, as shown in figure 2.1. Physical models may be those with which the general public are most familiar, but mathematical models are often used if the characteristics of the system concerned can be expressed using logical and quantitative relationships.

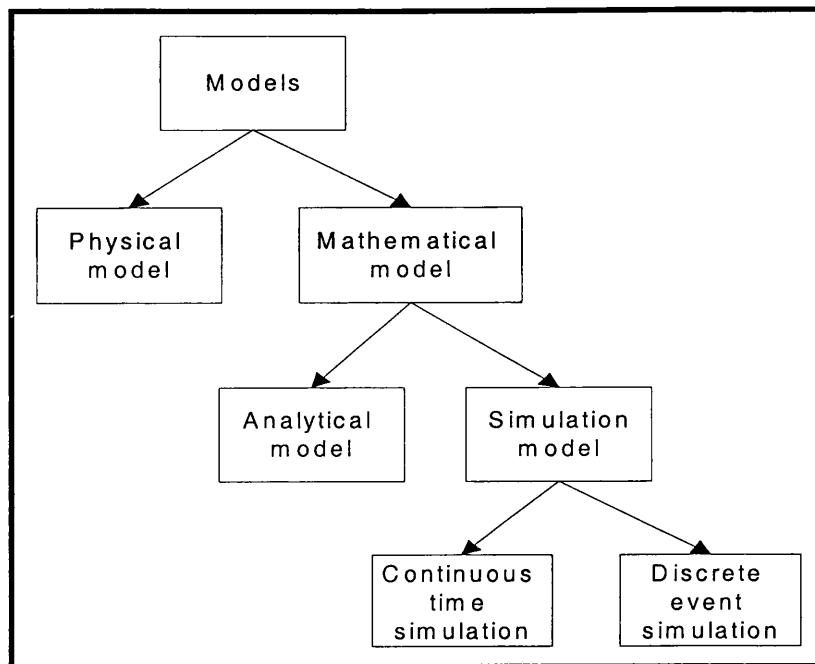


Figure 2.1 Types of model.

2.3 Mathematical models

The use of mathematical models to investigate problems and help in decision making is referred to as operational research. Such mathematical problem-solving techniques were first used in World War II for military purposes (Taha, 1995). After the war, the techniques that had been developed were expanded for use in business and industrial applications, and have more recently been applied to the field of health care (Jackson, 1985; Bachmann and Bevan, 1996; Michel *et al*, 1996). The general approach is to think of a problem as concerning a system of inter-related parts, with inputs and outputs. The key characteristics of the relationships amongst the different parts of the system are then represented mathematically and the resulting model manipulated to explore potential solutions to the problem.

There are two types of mathematical model: these are analytical models and simulation models (Law and Kelton, 1991; Pidd, 1998). Analytical models directly describe the

relationships amongst the inputs and outputs of a system and are solved using mathematical methods such as calculus, algebra or probability theory. In simulation models, the system of interest is instead broken down into separate components that are linked to each other by means of logical relationships. The behaviour of each component is then replicated as it occurs in the real world, usually using a computer, so that the behaviour of the whole system can be studied.

Simulation models are of many different types and can be classified in many different ways (Hoover and Perry, 1989; Law and Kelton, 1991). One such classification relates to whether the simulation is ‘continuous time’ or ‘discrete event’. In continuous-time models, the systems being modelled are represented as changing continuously over time. In discrete-event models, events are instead considered to occur at certain distinct times. Another distinction between the two is that continuous-time models focus on material in the aggregate while discrete-event models focus on individual items and their characteristics. The choice between these two approaches depends on the key characteristics of the system being modelled. For example, the administration of an intravenous infusion would be best represented using a continuous-time model, while the arrival and queuing of patients in a pharmacy would be best represented by a discrete-event model.

Another classification considers whether a model is deterministic or stochastic. A deterministic model does not contain any random or probabilistic components; the output is determined once the input parameters have been specified. A stochastic model, however, includes probability distributions and thus allows chance occurrences to influence the model’s output.

2.4 Stages of a mathematical modelling study

Stages of a typical mathematical modelling study are summarised in Figure 2.2 (Law and McComas, 1990; Law and Kelton, 1991; Oakshott, 1997).

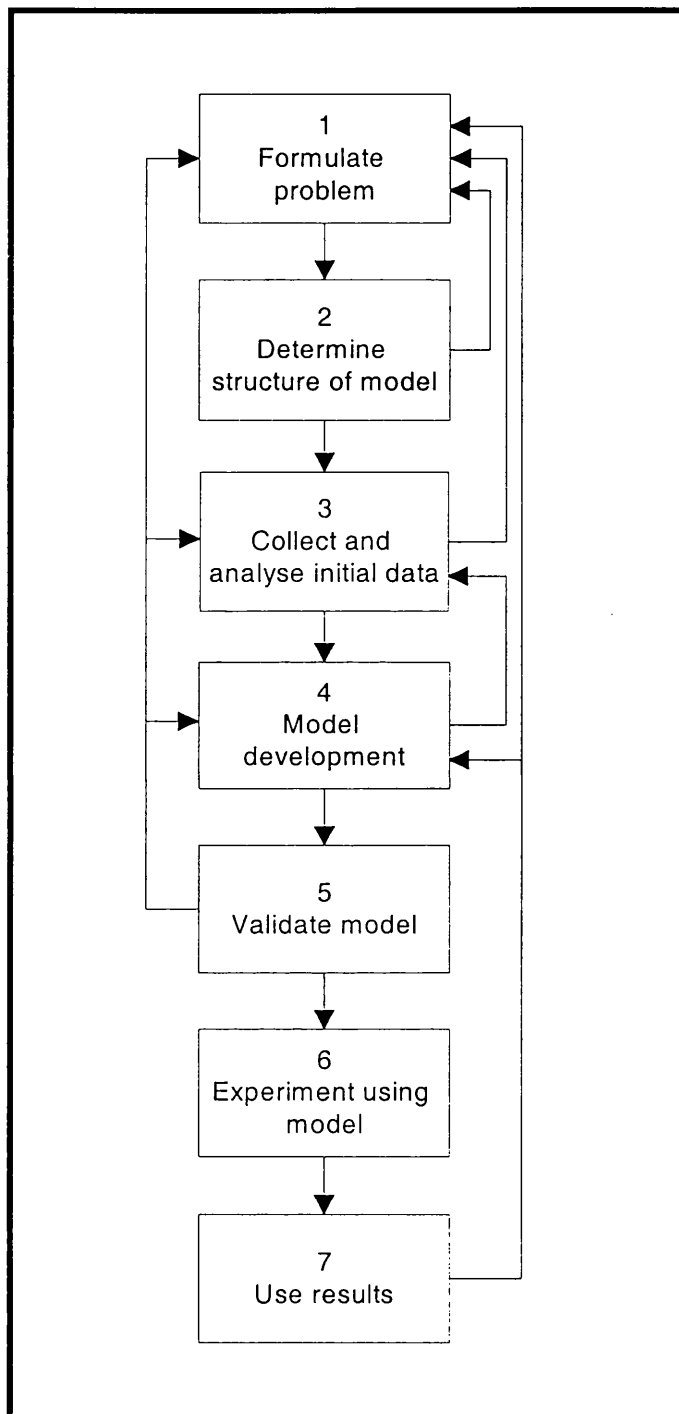


Figure 2.2 Stages of a mathematical modelling study.
The modelling process tends to take place iteratively, as indicated, rather than sequentially.

1. The problem is first carefully formulated in terms of the specific objectives and issues to be addressed. As with any experimental investigation, it is essential that the alternatives being compared and the criteria for their evaluation are specified.
2. The most appropriate type of model can then be selected and its structure determined. This aids the planning of data collection.
3. Data are collected and analysed. As with any other data collection exercise, data must be representative and sample sizes adequate.
4. The main model development stage then takes place. It is generally agreed that a model should initially be as simple as possible, with further enhancements added later if necessary. A model should only include enough detail to capture the important aspects of the system according to the purposes for which the model is intended; it is not necessary to have exact correspondence between all aspects of the real system and the model. Further data collection may be necessary as the model is developed. In the case of simulation models, a verification stage may also be included, which involves checking that the simulation model is working as intended and free from computer programming errors.
5. The next stage is usually to validate the model. Validation means finding out the extent to which a model is an acceptable representation of the real world. Often this requires additional data collection and analysis.
6. Once the model's validity is considered to be acceptable, experiments using the model can be designed. According to scientific method, initially one parameter is altered at a time and its effects on the model output explored. Subsequently the effects of altering more than one parameter may be investigated and interactions identified.
7. The results and conclusions obtained from the model can then be used in practice.

These processes tend to take place iteratively, rather than sequentially. For example, the data collected may suggest that the model's structure needs to be modified, while validation exercises might indicate that further data collection is necessary.

Mathematical modelling has been applied to many different problems in many different areas. In the next section of this chapter, some previous applications of mathematical modelling to pharmacy services will be considered.

2.5 Mathematical modelling of pharmacy services

There have been many reports of the use of mathematical modelling in health care. For example, mathematical models have been developed to evaluate clinical trials (Jackson and Aspden, 1979), compare treatment or screening options (Shahani *et al*, 1994; Sherlaw - Johnson *et al*, 1994) and monitor surgical performance (Lovegrove *et al*, 1998). Other models have been used to estimate the financial risks of rare but costly hospital referrals (Bachmann and Bevan, 1996) and to predict the health care services required by different patient populations (Davies and Davies, 1987; Michel *et al*, 1996). However, there have been only a few reports of the use of mathematical modelling in pharmacy practice. In this section, these studies will be described, giving consideration to the type of model and its purpose, inputs, outputs and validation.

One of the first studies that used mathematical modelling to investigate pharmacy services was published in 1972 (Myers *et al*, 1972). In this US study, a discrete-event simulation model of a hospital outpatient pharmacy was created using the programming language FORTRAN. This model was used to study the effects on patient waiting times of changing dispensing times or the priority rules for different prescription types. Inputs to the model were the frequency of incoming prescriptions and the dispensing times; these data were collected in the study hospital but the assumptions made in representing their distributions were not discussed. Outputs were the percentage of time that pharmacists spent dispensing and outpatient waiting times. The model was validated by comparing these outputs to those observed in the real world pharmacy. In a further study, the model

was used to explore the impact of prepacking medication or employing a label typist (Johnson *et al*, 1972).

Feiglin and Brooks (1973), in an Australian study, also constructed a FORTRAN discrete-event simulation model to explore how different operating conditions would affect patient waiting times in an outpatient pharmacy. Inputs were the times between successive arrivals and the times taken to complete the dispensing process; there was no mention of any model validation. The model was used to study the effects of pharmacists' tea breaks on outpatient waiting times; it was concluded that the average waiting time could be reduced from about 35 minutes to about 10 minutes by staggering the tea breaks (Brooks, 1972).

Harmon and Novotny (1974) used discrete-event simulation to compare five different options for reducing outpatient waiting times in a US military hospital pharmacy. Model inputs were prescription arrival rates, the time taken to type a label, the time taken to dispense the appropriate medication and the time taken to check the dispensed prescription. These data were collected during a six week period and distribution-fitting software used to select the most appropriate probability distribution to represent each variable. The model was constructed using the General Activity Simulation Program (GASP); output parameters were patient waiting times, the number of prescriptions in each stage of the system and personnel utilisation. Validation measures included a comparison of the model's output with actual patient waiting times. It was found that the waiting times predicted by the model were less than those experienced by real world patients; the authors suggest that this was because the model did not take into account interruptions to the dispensing process such as telephone calls. However, the model was considered sufficiently valid for its intended use.

Another US simulation study explored the effects of twelve different staffing arrangements on outpatient waiting times (Vemuri, 1984). A discrete-event model was created using the General Purpose System Simulator (GPSS) programming language. Inputs were the patient arrival rates and the times taken to complete each stage of the dispensing process. No validation of the model was discussed.

Moss (1987) also examined outpatient waiting times, but used an analytical rather than a simulation approach. Queuing theory, a branch of operational research devoted to the relationships amongst arrival rates, service times and waiting times in different types of queue (Taha, 1995), was used to investigate how the number of pharmacists employed would affect outpatient waiting times in a UK hospital pharmacy. Inputs were the number of pharmacists, the patient arrival rate and the distribution of dispensing times. Data describing patient arrival patterns and dispensing times were collected from three different hospitals. It was assumed that the dispensing times were distributed exponentially, but the mode rather than the mean of the empirical data was used in the calculations. No validation was described. The model developed was also used to compare the dispensing of prescriptions in series (where one member of staff receives the prescription, another labels, another dispenses and another checks the prescription) with working in parallel (where each member of staff completes one prescription from beginning to end). It was concluded that working in parallel would result in shorter waiting times than working in series. Series working can, however, be effective when it is possible to balance the workload optimally amongst the people in the production line (Hillier and Boling, 1979). This typically involves allocating higher workloads to the beginning and end of the production line, which may not be possible in the dispensing process where the greatest amount of work tends to be in the middle of the chain (labelling and dispensing).

Discrete-event simulation has been used in a study of variables affecting floor space requirements for intravenous admixture compounding units in US hospitals (Lin, 1992). A model of a compounding unit was constructed using SIMAN/Cinema, a simulation language that allows the model's behaviour to be animated. Inputs were the arrival rates for different types of compounding request; the output was the time taken to complete each compounding task. The minimum numbers of laminar-flow cabinets and personnel required to achieve specified service levels were then determined. Validation processes included face validation, in which the compounding unit manager examined the flow chart on which the computer model was based, and the comparison of the model's output with real world data.

More recently, discrete-event simulation has been used in the USA to predict whether a redesigned community pharmacy layout and work system could facilitate patient counselling without increasing waiting times (Lin *et al*, 1996). This model was also constructed using SIMAN/Cinema and for each of six pharmacies, was used to compare the existing configuration with the redesigned layout and work system. Inputs were patient arrival patterns, types of prescription and the time taken to perform each stage of the dispensing and counselling process, as well as the staffing patterns and layout for each pharmacy. Input data were collected using fixed-interval work sampling; the model was validated by comparing the predicted and real-world waiting times. It was concluded that with a redesigned pharmacy layout, increasing the level of patient counselling would increase patient waiting times slightly but would not require additional personnel. The new pharmacy layout and work system, in which technicians carry out labelling and dispensing, was then introduced in two of the six pharmacies, but the pharmacists resisted changing their work patterns and the full benefits of the new system may not have been achieved.

Most of these studies focused on US outpatient or community pharmacies. There are no reports of the application of mathematical modelling to the inpatient drug distribution system and only one of the above studies was carried out in the UK (Moss, 1987). In addition, only one of the studies cited describes the implementation of the results of a modelling study (Lin *et al*, 1996). The present study, which focuses on inpatient pharmacy services in a UK hospital, is therefore the first of its type.

The next chapter describes the preliminary stages of the modelling process, including a description of the drug distribution system at the study hospital and the selection of an appropriate modelling approach.

Chapter Three: Preliminary modelling work

3.1 Introduction

As discussed in the previous chapter, there are several stages involved in a mathematical modelling study. Initial steps include specification of the model's purpose and determination of the type of model required. It is also recommended that a prototype model is developed before any data collection is carried out, to ensure that data are collected in the most appropriate form (Law and Kelton, 1991).

This chapter describes the preliminary stages of the present modelling study, the aim of which was to explore the effects of different changes to the hospital drug distribution system on unavailability-related medication administration errors (U-MAEs). The drug distribution system at the study hospital will be described in detail before specifying the issues that the model was intended to explore. The rationale behind the modelling approach adopted will then be explained and an account given of the selection of an appropriate software package. The chapter concludes by describing the construction of a prototype model.

3.2 Objectives

1. To describe the drug distribution system at the study hospital.
2. To specify the purpose and scope of the modelling study.
3. To determine the most appropriate type of model with which to represent the drug distribution system.
4. To select the most appropriate software for the modelling study.
5. To construct a prototype model of the hospital drug distribution system.
6. To identify the model input variables for which values were required.

3.3 Description of the drug distribution system at the study site

The study was based at an 850-bed London teaching hospital that operates a drug distribution system based on ward pharmacy. This system will be described in detail, considering first the writing of medication orders, then the supply and dispensing of medication and finally its administration to the patient. The narrative concludes with an account of departmental opening times and the arrangements for medication supply during evenings and weekends. The drug distribution system in use at the study site is similar to those in use throughout the UK. This description focuses on the supply of medication to hospital inpatients; outpatient pharmacy services will not be considered.

3.3.1 Medication order writing

Each patient has a drug chart marked with their name and hospital number (Appendix 22). Medication orders are written by doctors directly onto these charts, which are usually kept on clipboards at the ends of patients' beds. Verbal medication orders are not permitted. The drug chart used in the study hospital contains four main sections: medication to be given regularly, intravenous infusions, medication to be given when required and medication to be given once only. Each section is formatted to prompt the prescriber for the information required. For example, the section for regular medication has spaces for the drug name, the dose, the route of administration, the start date, the duration of therapy, the doctor's signature and any additional instructions. In addition, there are six times printed at which medication can be administered, namely 6 am, 8 am, noon, 2 pm, 6 pm and 10 pm. These times correspond to the theoretical times of the nurses' drug administration rounds. The prescriber circles the times at which each drug is to be given, for example a drug to be given four times a day could be given at 6 am, noon, 6 pm and 10pm. If the prescriber wishes doses to be given at different times to those indicated, he or she can also specify alternative times. For each drug prescribed, the drug chart also contains spaces corresponding to each administration time in which the nurses sign for the administration of each dose.

Once a medication order has been written, the drug concerned can be administered as

soon as the drug is available on the ward. It is not necessary for medication orders to be checked by a pharmacist prior to administration.

3.3.2 Supply of medication

Arrangements for supply depend on whether the drug concerned is a stock drug, a non-stock drug or a controlled drug ¹.

3.3.2.1 Stock Drugs

Each ward stocks a selection of commonly used drugs, usually enough to provide about 80% of all doses needed. One bottle or box of each oral stock drug is stored in a lockable drug trolley. Additional supplies of each oral stock drug and all other stock drugs are stored in locked cupboards. Medication that is available from the manufacturer in appropriately-sized packs is stocked on the ward in these packs. Medication that is only available in very large containers is repackaged in the pharmacy department into ward packs, each of which is labelled with the drug's generic name, dosage form, strength, expiry date, batch number and quantity. Where drugs are supplied in their manufacturers' original packaging, their labels also include the drug's brand name, license details and other information.

Ward supplies of stock medication are replenished by pharmacy technicians who visit each ward between one and three times a week, depending on the ward's medicine usage. The technicians use bar-coded stock lists that indicate the quantity of each drug that should be kept on each ward; these stock levels are determined according to previous usage patterns and modified when necessary. The technicians inspect the ward drug cupboards, check medication expiry dates and record any shortfall in the amount of each drug onto the stock list; this information is later entered into the pharmacy computer system using a bar code scanner. A list of the drugs required for each ward is then printed, which is used to select the drugs required. The drugs selected for each ward are

¹

'Controlled drug' is used here to refer to any drug listed in schedule 2 of the 1971 Misuse of Drugs Act. These drugs are kept in a locked controlled drugs cabinet and additional records are made for each administration.

placed in a delivery box, which is transported to the ward by a porter and unpacked by the nursing staff.

If ward supplies of any stock medication become depleted between the technician's ward visits, nursing staff contact the pharmacy department to request additional supplies.

3.3.2.2 Non-stock drugs

Drugs that are not on the ward's stock list are dispensed in the pharmacy department for individual patients when necessary.

Ordering

Non-stock drugs are not generally ordered until a nurse sees the new medication order on the drug chart; this is usually during the next scheduled drug administration round. If the nurse perceives the drug to be required urgently he or she may take the drug chart to the pharmacy department and ask for the drug to be dispensed. Otherwise, the nurse writes the name of the patient and the drug required onto an order form attached to the drug trolley.

The ward pharmacist's role

Each ward is assigned a pharmacist who visits twice daily from Mondays to Fridays. The times of these visits vary, but 9 am and 2 pm are fairly typical. On Saturday mornings a pharmacist briefly visits each ward; there are no visits on Sundays. Some pharmacists are responsible for more than one ward; others also attend consultant ward rounds or have other clinical roles at ward level.

During each ward visit, the pharmacist checks the drug trolley order form to identify any patients for whom drugs are needed. He or she then enters the details of any drugs required onto a ward pharmacy order form, including the patient's name, the drug, strength and number of dose units required. Once daily on Mondays to Fridays the pharmacist also examines each patient's drug chart to check that all medication orders are clear, legal and clinically appropriate for the patient concerned. Any clinical issues are discussed with the prescriber or nurse, as appropriate. Each drug chart is then annotated

with additional information such as drugs' generic names and administration instructions. There is a small pharmacy section on the drug chart for each drug prescribed, into which the pharmacist writes an *S* for any drug that is stocked on the ward and a signature, date and amount dispensed for any non-stock drugs supplied. The quantity of each drug dispensed is based on the pharmacist's discretion. Typically one week's supply of each drug is supplied, but the pack size and the patient's anticipated length of stay may also be taken into account.

Before the dispensed supply of a non-stock preparation becomes depleted, a further supply should be made. Some pharmacists periodically check the supplies of non-stock medication in the drug trolley, some anticipate when a further supply should be made based on the quantity previously supplied and others wait for nursing staff to reorder medication on the drug trolley order form.

Once the pharmacist has entered details of all drugs required onto a ward pharmacy order form, it is delivered to the pharmacy department either by the pharmacist in person or via the hospital's pneumatic tube system.

Dispensing

Following their receipt in the pharmacy department, the ward pharmacy order forms are prioritised according to hospital wing then dispensed on a first-in, first-out basis. Most dispensing is carried out by technicians or pharmacy assistants.

The dispensing process begins with the production of a label using the pharmacy computer system. The patient's name and ward are first entered, followed by details of the drug concerned. This is entered in a shorthand format consisting of the first three letters of the name, the first two digits of the strength and the first letter of the dosage form. For example prochlorperazine 5mg tablets would be entered as PRO05T. The computer system then produces a list of all the drugs that meet this description; in this example this would include procyclidine 5mg tablets as well as prochlorperazine 5mg tablets. The appropriate drug is then selected and the required number of dose units entered. The computer system performs a stock control function and automatically places

an order with an on-site warehouse for any drugs whose stock level has fallen below a predefined minimum.

Once the label has been produced, specifying the patient's name, ward, drug name, quantity and dispensing date, the drug is located on the dispensary shelves. The appropriate number of dose units are placed in a container, to which the label is added. Loose tablets are packed in bottles, blister-packed tablets in boxes. Additional labels are added to specify the medication's expiry date, batch number and any relevant storage instructions. Dispensed medication is then placed with the corresponding ward pharmacy order form into a tray for checking.

A pharmacist checks all technicians' and assistants' dispensing, signs the ward pharmacy order form and puts the dispensed items into the appropriate ward delivery box. Items dispensed and labelled by a pharmacist do not have to be checked by a second person. The ward pharmacy order forms are filed in the pharmacy department.

Delivery to the ward

Ward boxes containing dispensed medication are delivered to each ward at about 12:30 pm, 2 pm, 3:30 pm and 5:30 pm each weekday and at about 12:30 pm on Saturdays. The contents are then unpacked by the nursing staff and placed in the drug trolley. If any medication is dispensed after 5:30 pm on weekdays or after 12:30 pm on Saturdays, a nurse from the ward concerned must collect the dispensed medication.

3.3.2.3 Controlled Drugs

Controlled drugs are stored in a locked cabinet on each ward and ordered when necessary by the ward sister or acting sister. A dedicated order book is used, with duplicate numbered pages. The sister writes each order onto a separate page of the book, which is then sent to the pharmacy department. Following dispensing, the top copy is kept in the pharmacy; the bottom copy remains in the order book which is returned to the ward with the dispensed drugs. The person responsible for transporting the drugs to the ward must sign the book, as must the nurse who receives them. All issues and receipts are recorded on each ward and in the pharmacy department. Whenever a nurse administers a dose of a

controlled drug, details of the patient, date, time and dose given are recorded in a controlled drugs register and checked by another nurse.

3.3.3 Medication administration

Drug administration rounds are carried out by nursing staff up to six times a day, corresponding to the times indicated on the drug chart. On many wards, the 6 am and 8 am rounds and the noon and 2 pm rounds are combined. During each drug round, the drug trolley is unlocked and wheeled from bed to bed. Each patient's drug chart is examined to identify any oral, inhaled, ocular, aural or nasal doses due at that time. The appropriate medication is then selected from the drug trolley and administered to the patient. The drug chart is signed by the nurse in the administration box corresponding to the relevant drug, date and time. Each drug chart has space for two weeks' medication administration to be recorded; after this time a doctor must rewrite the chart. Because the drug trolley does not contain supplies of any controlled, injectable, topical or rectal medication, doses of these drugs are administered separately. If any oral medication is required between scheduled drug rounds, the relevant doses are selected from the drug trolley and taken to the patient for administration.

If a scheduled dose is not given for any reason, the nurse should enter a cross in the appropriate administration box on the drug chart and record the reason for non-administration in a separate section on the back of the drug chart. The administration of drugs that patients have brought in from home is not permitted and only medication supplied by the hospital pharmacy can be used.

Occasionally doses of intravenous drugs are administered by doctors, but nurses perform the majority of drug administrations. Trained nurses may administer medication alone, with the exception of doses of intravenous and controlled drugs which must be checked by a second nurse.

3.3.4 Hours of service

3.3.4.1 Weekdays

The pharmacy department is open from 8:30 am until 5:30 pm. However, at least one pharmacist remains in the department until about 6 pm or until all medication has been dispensed and taken to the appropriate wards.

3.3.4.2 Weekends

The pharmacy department is open on Saturday mornings between 9 am and 12:30 pm, and on Sunday mornings between 10 am and noon. On Saturday mornings a pharmacist briefly visits each ward to check the drug trolley order forms. On Sundays there are no ward visits and nursing staff must take drug charts to the pharmacy department if any medication is required. Again, pharmacy staff do not leave until all medication has been dispensed and delivered to the wards.

3.3.4.3 Out of hours service

Whenever the pharmacy department is not open, a pharmacist is available on site and can be reached via a pager. This resident pharmacist dispenses any stock or non-stock drugs urgently required and provides an information service.

3.4 Purpose and scope of the modelling study

There are a number of ways in which changes could be made to the drug distribution system described, each of which could affect the incidence of U-MAEs. Relatively simple changes include altering the times of the porters' deliveries, the pharmacists' ward visits or the pharmacy opening hours. Other potential changes include the introduction of computerised prescribing, electronic mail or fax systems to increase the speed of information transfer between the ward and pharmacy department.

Other factors that would be expected to affect the U-MAE rate relate to patient and ward characteristics. For example, an increased rate of patient turnover may increase U-MAEs if patients are prescribed non-stock medication on admission which is then unavailable

for the first part of their hospital stay. An objective of the present study was therefore to develop a model that could be used to predict the effects on the U-MAE rate of various changes to the drug distribution system, for different patient groups on different hospital wards. The desired model output was the percentage U-MAE rate. Inputs included patient characteristics, ward characteristics and the configuration of the drug distribution system (figure 3.1).

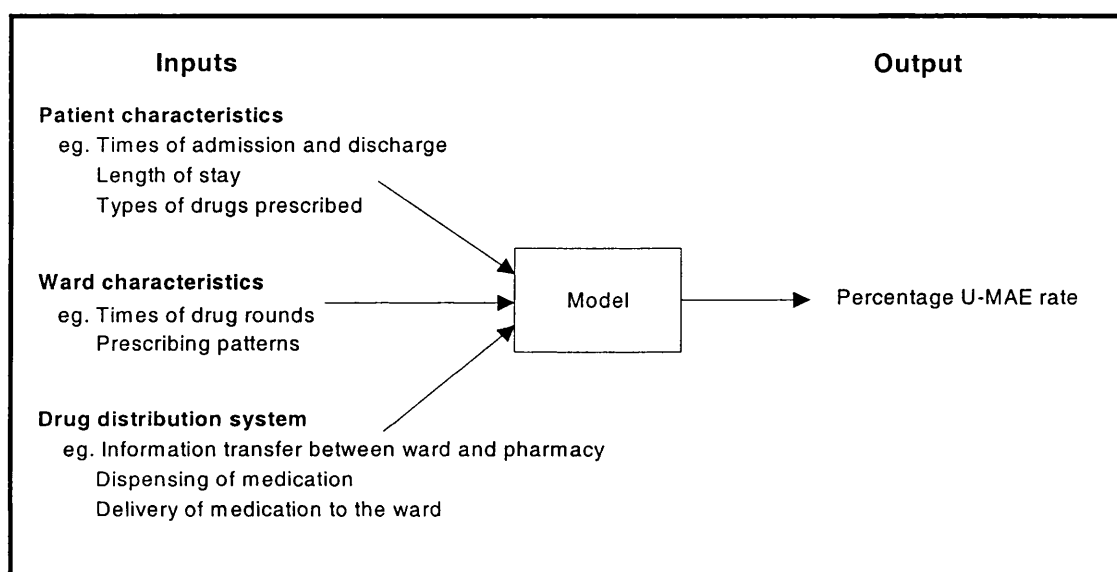


Figure 3.1 Summary of model inputs and output.

It was decided to limit the scope of the model to regularly prescribed doses administered from the drug trolley during scheduled drug administration rounds. These included all regularly scheduled oral, inhaled, ocular, aural and nasal preparations but excluded controlled, injectable, rectal and topical doses. This was to allow meaningful comparison of the model's output with data obtained from the observation of drug rounds. Drugs to be given once only and when required were also excluded to facilitate data collection, as these represent only a small proportion of doses given. It was estimated that the doses included would represent at least eighty percent of the doses given on the majority of hospital wards.

3.5 Choice of modelling approach

The first choice that had to be made was between an analytical model and a simulation model. Analytical models can be quicker to develop and allow an exact solution to be calculated, while simulation models are generally more time-consuming to construct and can give only estimates of the output parameters (Law and Kelton, 1991). However, simulation allows greater flexibility in representing complex stochastic systems. Many parts of the hospital drug distribution system involve stochastic variables; these include the times at which prescriptions for different types of drug are written, the times at which pharmacists visit their wards and the delays incurred during dispensing. Furthermore, the characteristics of many of these variables change according to the time of day. It was therefore considered that a simulation approach would be the most appropriate for the present study.

The second issue was whether a discrete-event or a continuous-time simulation model should be used. The drug distribution system concerns events that take place at distinct times and involves the processing of individual items (medication orders), each of which can have different characteristics. A discrete-event simulation model was therefore considered the most appropriate for the present study. The next stage was to select the most appropriate software with which to construct such a model of the hospital drug distribution system.

3.6 Selection of simulation software

In the past, the construction of simulation models required extensive computer-programming expertise, expensive software, or both. Now, the availability of relatively inexpensive personal computer (PC) based simulation packages has made simulation more accessible as a problem analysis tool. Many of these packages are based on a graphical interface and do not require prior programming experience (Hansen, 1994; Tyo, 1995; Cummings, 1997). However there is a confusing array of simulation packages available and it was not clear which would be the most suitable for the present study.

It has been suggested that a structured approach should be taken to selecting simulation software, so that all the important factors are taken into account and the most appropriate choices made (Hlupic and Paul, 1996). It was therefore decided to construct simplified models of the hospital drug distribution system using several different simulation packages and then use each of these models to investigate a simple question. The specific strengths and weaknesses of each package could thus be identified in relation to the present study. The next section describes the methods used to select the most appropriate software for the present study.

3.6.1 Methods used for software selection

3.6.1.1 Initial selection of software

A recent survey of simulation packages was used to select a short list of those potentially suitable for use in the present study (Swain, 1995). To be included in the short list, software packages had to meet the following screening criteria:

1. Priced in the UK at less than £500, after taking into account any academic discounts available.
2. Described as being suitable for general-purpose discrete-event simulation.
3. Suitable for use on an IBM-compatible PC with 16 Mb of RAM and a 90 MHZ Pentium processor, running Windows 95.
4. Model construction carried out using a graphical interface rather than a programming language.

3.6.1.2 Structure of model

The short-listed packages were each used to construct a simplified model of the ward pharmacy system, as shown in figure 3.2. Medication orders were considered to be written by medical staff at independent times before being subjected to a series of delays as they awaited the ward pharmacist, subsequent dispensing and delivery to the ward.

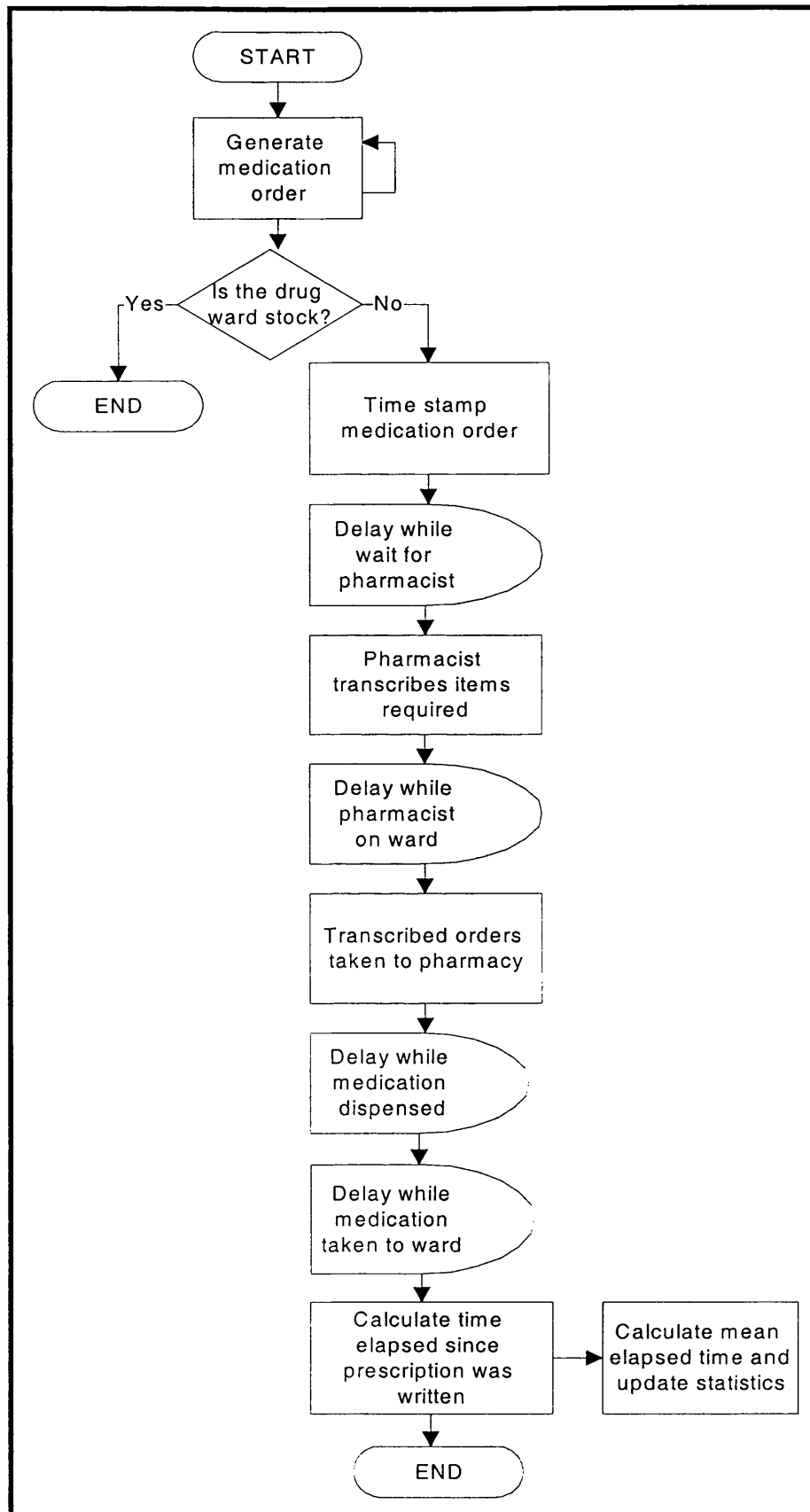


Figure 3.2 Structure of a simplified model of the ward pharmacy system. Models corresponding to this structure were constructed using each short-listed software package.

3.6.1.3 Data sources

For the purposes of this preliminary study, existing data sources were used to obtain information on the frequency of medication order writing, the time taken for ward pharmacists to carry out their duties and the time taken for medicines to be dispensed and delivered to the ward. Data from two orthopaedic wards in different hospitals (Bottomley, 1993; Hartland, 1996), a care of the elderly ward (Ho *et al*, 1997) and a medical ward (Hartland, 1996) were used to estimate the mean time between successive medication orders at different times of day on different wards. These figures were adjusted where necessary to give the expected medication order rates for a 30 bed ward. Information describing the times taken by ward pharmacists to complete their ward visits was obtained from a recent survey (Batty and Dhillon, 1997); data describing the times taken to dispense and check medication orders were estimated from in-house data at the study hospital. A distribution-fitting package (BestFit version 2.0d, Palisade Corporation, Newfield, New York) was used to identify the theoretical statistical distribution that best described each set of data. Details of the distributions used and the assumptions made during this preliminary study are given in Appendix 1.

3.6.1.4 Model construction and verification

Models corresponding to the structure shown in figure 3.2 were constructed using each short-listed package. For simplicity during this preliminary study, the models were constructed to output the mean time delay between the prescription of a non-stock drug and its delivery to the ward, instead of the percentage U-MAE rate.

The models constructed were verified by checking that certain values were appropriate, for example that the number of unsupplied non-stock medication orders rose throughout the day and night and then fell to zero following the ward pharmacist's visit. Different input parameters were then changed and it was confirmed that specific values in each model increased or decreased as expected.

3.6.1.5 Model experimentation

In order to assist with the evaluation of each software package, each model was used to

explore a simple problem. The issue chosen for investigation was the relationship between the number and times of the ward pharmacist's visits and the mean time delay between the prescription of a non-stock drug and its delivery to the ward. Four decision alternatives were proposed:

1. One daily ward visit at 9 am.
2. One daily ward visit at noon.
3. One daily ward visit at 3 pm.
4. Two daily ward visits, at 9 am and 2 pm.

The length of each model run was 7 simulated days. The first two days' data were discarded to allow the system to reach steady-state; results were then collected for the five subsequent days. Thirty independent runs were made for each of the 48 different combinations (four different visit times, four sets of ward prescribing times data and the three software packages), using different sequences of random numbers to generate the medication orders. For each set of thirty results, the overall mean time delay and its 95% confidence interval were calculated.

3.6.1.6 Evaluation framework

An evaluation framework based on Hlupic's (1997) was used to assess the short-listed packages. The following aspects were considered; these are listed in the order given by Hlupic, which does not correspond to their order of importance:

1. General features (how easy it is to learn and use the package, level of prior experience necessary).
2. Visual aspects (graphics and animation; these features aid model verification and interpretation of the results).
3. Coding aspects (whether the package allows additional programming for specific applications).
4. Efficiency (time taken to construct and run a model).
5. Testability (whether the package allows trace files to be generated to give a

detailed account of the simulation's behaviour).

6. Input (range of theoretical statistical distributions, ability to use user-defined distributions).
7. Output (range and flexibility of output formats).
8. Statistical features (includes control of random number generator, which is important during model experimentation).
9. User support.
10. Cost.

Each software package was given a subjective score of between 1 and 10 for each of these aspects, where 1 represents very poor quality or absence of the feature and 10 represents excellent quality (Hlupic, 1997).

3.6.2 Results

3.6.2.1 Initial selection of software

Application of the screening criteria resulted in a short list of three packages: Extend version 3.2 (ImagineThat!, San Jose, California), Ithink version 3.0.6 (High Performance Systems, Hanover, New Hampshire) and Simul8 version 3.0 (Visual Thinking International, Glasgow).

Extend

Extend is designed for use in continuous-time, discrete-event and combined models. Models are constructed by selecting building blocks and making connections amongst them on the computer screen. The standard package includes ninety different types of building block, each of which can be modified using its associated menu. Additional libraries of building blocks can be purchased for specific applications. Blocks can be further modified and new ones created using a built-in programming language similar to C++.

Ithink

Ithink is based on Forrester's system dynamics approach (Forrester, 1990), in which every concept is represented as a stock, a flow or a converter. Stocks are used to represent accumulations of material, such as dispensed medication orders awaiting delivery to the ward. Flows are used to represent any process that fills or drains a stock, such as the delivery of dispensed medication to the ward. Converters contain information, such as the times at which pharmacists visit the ward. Relationships amongst different parts of the model are specified using an algebraic notation. Although the system dynamics approach is usually applied to continuous simulation, Ithink software includes features to model queuing and the manufacturers suggest that it can also be used for discrete-event simulation.

Simul8

Simul8 is specifically designed for discrete-event simulation. Models are constructed using combinations of six building blocks. These represent the generation, storage, processing and removal of items, conveyer belt processes and resources (such as workforce). Each block is associated with a menu via which various parameters can be altered, so that each type of building block can be used to represent many different processes. Additional inputs and outputs can be created with Visual Basic or Excel software.

3.6.2.2 Model construction

Appendices 2, 3 and 4 show the on-screen appearance and relevant documentation for the models created using Extend, Ithink and Simul8 respectively.

3.6.2.3 Simulation results

The simulation results are summarised in figures 3.3, 3.4 and 3.5. Similar conclusions were reached using each package. On three of the four simulated wards, later visits were predicted to reduce the mean delay between the prescription of a non-stock drug and its delivery to the ward, although the relative benefits of the different visit times varied amongst the wards. On the first orthopaedic ward and the care of the elderly ward any

additional benefit of a twice daily visit is small, whereas for the medical ward and the second orthopaedic ward a second daily visit significantly reduces the mean delay time. For the medical ward, there is little difference between a 9 am visit and a 3 pm visit whereas a noon visit results in significantly longer mean delay times. This finding can be explained by the fact that the majority of prescribing on this ward takes place during the afternoon. A predicted reduction in the mean delay time of up to 14 hours could be achieved by changing the pharmacist's visit schedule, according to the results for the care of the elderly ward obtained using Ithink.

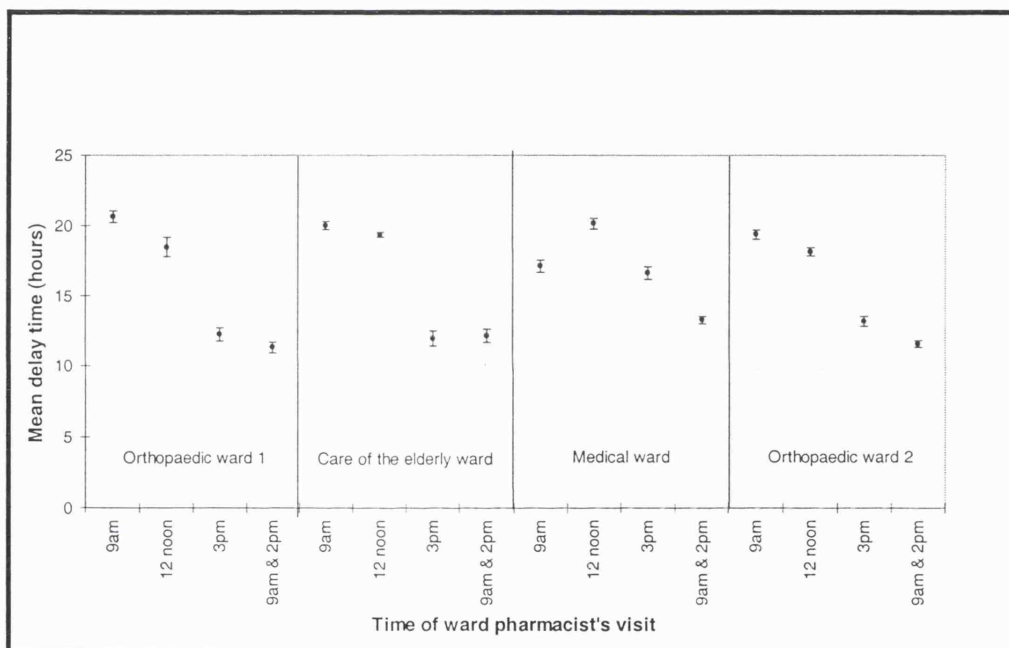


Figure 3.3 Software evaluation: results obtained using the Extend model.
Bars represent 95% confidence intervals for the mean.

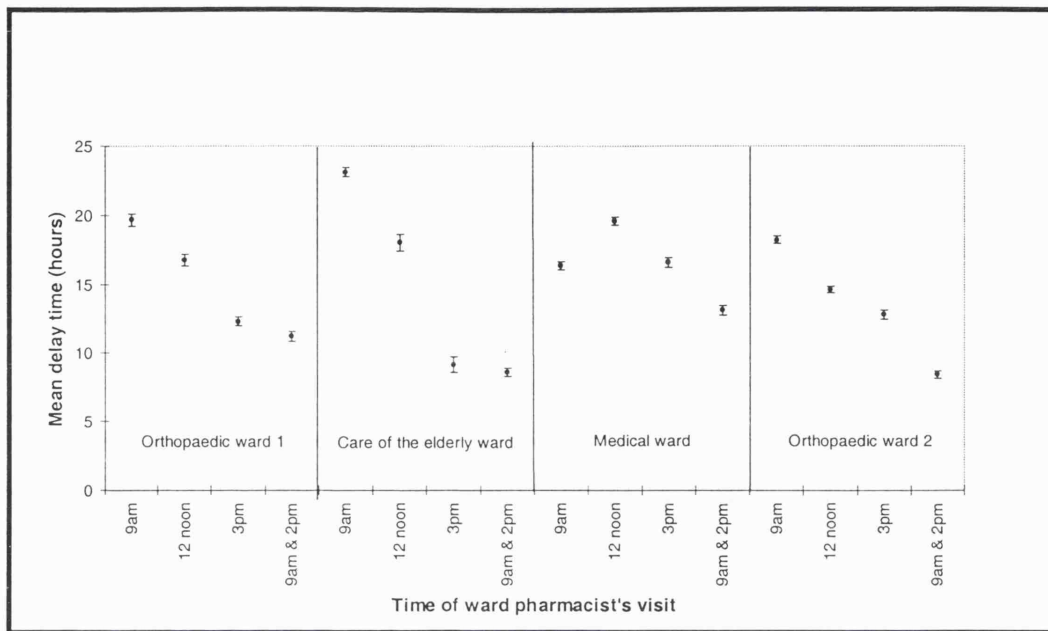


Figure 3.4 Software evaluation: results obtained using the Ithink model.
Bars represent 95% confidence intervals for the mean.

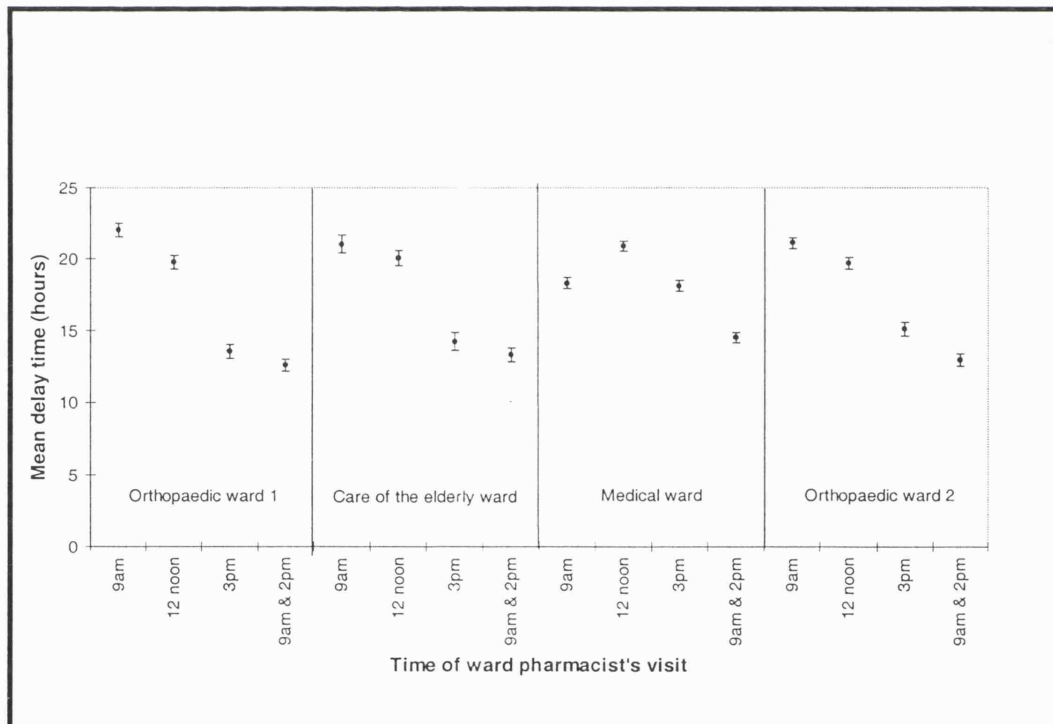


Figure 3.5 Software evaluation: results obtained using the Simul8 model.
Bars represent 95% confidence intervals for the mean.

3.6.2.4 Software evaluation

A summary of each package's performance with respect to each evaluation area is given in table 3.1.

	Extend	Ithink	Simul8
General features	7 *	5	6
Visual aspects	7	5	9
Coding aspects	10	1	5
Efficiency	9	7	8
Testability	9	2	7
Input	9	3	7
Output	9	7	5
Statistical features	8	5	8
User support	9	7	7
Cost	7	10	8
TOTAL	84	52	78

Table 3.1 Comparison of the three short-listed software packages.

* Numbers represent scores between one (very poor) and ten (excellent).

General features

Overall, Simul8 was considered the easiest software to use. However, this package is relatively new and the version used in this study contained a number of programming errors. The main problem experienced was that the model worked correctly only when the time units were set as minutes; the model would not run when the time units were hours. Future versions of the software will undoubtedly overcome such problems.

Extend was more difficult to learn although it is potentially more flexible once the user is familiar with its functions. The Ithink package is itself fairly easy to use, but it was difficult to use it to construct a discrete-event model. Another difference between the packages relates to the ease with which a model's construction can be documented.

Extend and Ithink can both generate text files of a model's structure and associated input

parameters, while there is no corresponding feature within Simul8.

Visual aspects

Simul8 has the best animation features; these show the movement and accumulation of simulation items and can be used to give a clear visual representation of any delays or bottlenecks. The on-screen appearance is also clear and intuitive and the model building blocks look like the processes they represent. Extend's animation facilities generally involve only flashing icons, the appearance of which are less meaningful. In Ithink, only stocks can be animated.

Coding aspects

Extend's building blocks can be modified and new ones created using a built-in programming language. Although requiring some experience with programming techniques, this facility means that blocks can be created to represent a very wide range of specialised situations. The algebraic notation within Ithink is relatively flexible but no additional coding is possible. Coding is possible with Simul8 but this requires the purchase of Excel or Visual Basic and was therefore not tested in the present study.

Efficiency

The time taken to build and run the test model varied amongst the three packages, although this may have been affected by the order in which the models were constructed. The Simul8 model was constructed first and required 4 days, followed by the Extend model which took 3 days; finally, the Ithink model required 5 days to complete and run. Constructing the Ithink model took only 2 days, but since a set of thirty runs took over one hour to complete, the total time required was longer than for the other two packages, in which each set of thirty runs took less than two minutes. Much of the time taken constructing the Simul8 model was spent trying to get the model to run when the time units were set as hours, as previously discussed.

Testability

Extend allows both simulation reports and traces to be produced. Reports are text files

that show the final value associated with each model building block, while traces give the status of each block at every simulation step. There are no equivalent features in Ithink, although output tables can be used to record relatively detailed information. Simul8 allows the user to view the next scheduled simulation event and the previous 100 events. Extend and Simul8 models can also be run one step at a time to determine the order in which simulation events occur.

Input

Extend allows the user to generate values from the binomial, Erlang, exponential, hyper-exponential, lognormal, normal, Poisson, triangular, uniform and Weibull theoretical distributions, as well as empirical distributions based on tabulated data. Ithink only includes the exponential, normal or Poisson distributions. In the present study, values from an Erlang distribution were required; these therefore had to be generated using the sum of the appropriate number of exponential distributions (Taha, 1995). Ithink also allows empirical graphical distributions to be created from tabulated data. Simul8 provides the beta, exponential, gamma, lognormal, negative exponential, normal, triangular, Pearson V and VI, uniform and Weibull distributions. Other distributions can be defined in Excel and then linked to Simul8.

Output

A number of standard output formats are included within Simul8. These include parameters such as the percentage of simulation items that spend more than a specified time in the simulated system and the minimum, maximum and mean delay times. However any additional tailoring of models' output requires the addition of Excel. Extend provides a wider range of output formats and can be further enhanced by pasting the output values into a spreadsheet, in which calculations can be performed and user-defined graphs produced. Ithink is not easy to link to a spreadsheet but output formats are relatively flexible and include both graphical and tabular formats.

Statistical features

Extend and Simul8 both allow either the same stream or different streams of random

numbers to be used for successive replications of a model. Ithink allows the replication of random numbers within each random function, but the random number seeds have to be changed individually each time a different but repeatable stream of random numbers is required.

User support

Extend has excellent documentation and technical support. Simul8 also has excellent technical support but the user manual, although well-written, is less comprehensive. The Ithink manual is easy to use and very comprehensive; no attempts were made to contact the technical support department during this study.

Cost

At the time of purchase (October 1996) the academic prices for Extend and Ithink were \$495 (about £300) and £100 respectively. Academic prices were not available for single copies of Simul8, but the full-priced version cost only £245.

3.6.3 Discussion

In this preliminary study, simulation was found to be a fast and non-disruptive way to explore the relationship between the time of the pharmacist's visit and the efficiency of the medication supply process. Reassuringly, the conclusions drawn were identical for all three packages tested. Most importantly, the construction of models using each software package allowed their advantages and disadvantages to be identified in relation to the present study.

Only the basic software packages were tested in this preliminary study. Extra libraries of building blocks can be purchased for Extend, and Simul8 can be enhanced by linking it to Visual Basic or Excel. The evaluation results also apply only to the specific versions of each package tested.

It was concluded that Ithink was not appropriate for the present study. Although

described as being suitable for both discrete-event and continuous-time simulation (Swain, 1995), this package is clearly more suitable for continuous-time and system-dynamics modelling (Burnstein, 1995). However, Simul8 and Extend were both found to be appropriate for modelling the hospital drug distribution system. Simul8 is easier to use, particularly for newcomers to simulation, but Extend is more flexible and has a wider range of features. It was therefore decided to use Extend to construct a more comprehensive model of the hospital drug distribution system.

3.7 Construction of a prototype model

The next stage of the study involved the construction of a more comprehensive prototype model using Extend. This model was based on that developed for the purposes of software evaluation (section 3.6) but with the level of detail increased. For example, the model was modified to make the principal output parameter the percentage U-MAE rate instead of the mean time delay between the prescription of non-stock medication and its delivery to the ward. This modification involved the simulation of drug rounds and the inclusion of medication order discontinuation as well as medication order writing. Further modifications included the incorporation of patient admissions and discharges and the classification of simulated medication orders into those written on admission and those written during the remainder of a patient's stay.

During the construction of this model, it was realised that the purchase of two additional libraries of Extend building blocks would be necessary. The Manufacturing library contains a more comprehensive selection of discrete-event blocks; the Statistics library includes blocks that summarise model statistics and give greater control over the generation of random numbers. Blocks from these libraries, as well as those from the standard Extend libraries, were therefore used in model construction. It was also decided to upgrade to Extend version 4 when it was released, as this substantially reduced the time taken to complete each model run.

Once the prototype model had been completed, a list was made of those input variables

for which data were required. These were as follows:

1. Times and frequencies of medication order writing and discontinuation.
2. Characteristics of the drugs prescribed; these included whether or not drugs were ward stock, whether or not drugs were taken by the patient prior to their admission and the dose regime prescribed.
3. Times and frequencies of patient admissions and times of discharge.
4. Ward length of stay.
5. Times and durations of pharmacists' ward visits.
6. Delays incurred during the dispensing of non-stock medication.
7. Times and durations of porters' ward deliveries.
8. The frequency with which drugs are obtained from the pharmacy department between ward pharmacists' visits.

The information regarding whether or not drugs were taken by the patient prior to their admission was required so that alternative systems such as the use of patients' own drugs could be studied. Patients would be likely to have supplies of only those drugs that they were taking prior to their admission.

The next chapter describes the data collection carried out and the selection of parameters to represent each of the variables listed.

Chapter Four: Data collection

4.1 Introduction

The construction of a prototype model (section 3.7) allowed the identification of those model variables for which data were required. This chapter gives an account of the data collection carried out and explains how parameters describing each of these variables were selected. First, however, the selection of the study wards will be described.

4.2 Objectives

1. To select one or more study wards.
2. To estimate appropriate parameters to describe each of the following, for each ward:
 - i. Times and frequencies of medication order writing and discontinuation.
 - ii. Characteristics of the drugs prescribed.
 - iii. Times and frequencies of patient admissions and times of discharge.
 - iv. Ward length of stay.
 - v. Times and durations of the pharmacist's ward visits.
 - vi. Delays incurred during the dispensing of non-stock medication.
 - vii. Times and durations of porters' ward deliveries.
 - viii. Frequency with which drugs are obtained from pharmacy between the ward pharmacist's visits.

4.3 Selection of study wards

It was decided to collect data on two wards, one medical and one surgical, so that a model of each could be constructed. It was considered that the collection of data on only one ward would severely limit the study's conclusions, while data collection on more than two was not possible within the time available.

The nature and purpose of the study were described to the ward sisters of all general medical and general surgical wards in the study hospital, and volunteers sought from amongst these staff. Sisters from one medical ward and one surgical ward indicated their interest; the researcher therefore met with nursing staff on each of these wards to discuss the study in more detail. Staff on both wards agreed to take part; the characteristics of each ward will now briefly be described.

4.3.1 Surgical ward

The 28-bed surgical study ward specialised in vascular surgery although some general surgical patients were also admitted. Drug rounds were nominally carried out at 6 am, noon, 6 pm and 10 pm; all doses scheduled for 8 am were administered at 6 am and all 2 pm doses at noon. In practice, the drug rounds took place from about 5:30 am until 7:30 am, from 11:15 am until 12:15 pm, from 5:30 pm until 6:30 pm and from 9:45 pm until 11:00 pm.

4.3.2 Medical ward

The medical study ward opened in January 1997 and specialised in renal medicine; general medical and renal transplant patients were admitted occasionally. The ward had 16 beds; drug rounds were carried out at similar times to those on the surgical ward but were generally of a shorter duration.

4.4 Distribution fitting

Many of the variables of interest (ward length of stay and dispensing times, for example) can take on a wide range of values and were considered to be best represented using probability distributions. The use of summary statistics such as the mean to represent such data would conceal their variability, which is likely to be an important characteristic of the drug distribution system. It was therefore necessary to select distributions to represent many of the model's input variables. In such cases, it is recommended that theoretical distributions are used wherever possible, instead of empirical distributions

based on the raw data values themselves (Law and Kelton, 1991). This is for three reasons. First, where only a small sample of data is available, irregularities may exist that are not representative of the wider population; using a theoretical distribution ensures that these are smoothed out. Second, use of a theoretical distribution allows the generation of rare extreme values that may not have been observed in a small number of data values. Provided these extreme values are appropriate, a theoretical distribution can more accurately represent the variability of the data concerned. Finally, from a practical point of view, a theoretical distribution is a compact and efficient way to describe a set of data values and reproduce them in a simulation model.

Whenever a distribution was required to represent a variable in the present study, the following steps were taken with the aid of distribution-fitting software (BestFit version 2.0d, Palisade Corporation, Newfield, New York). First, a histogram of the data was produced and examined visually. Second, maximum-likelihood estimators were determined for potentially suitable families of distribution (Law and Kelton, 1991). In the case of continuous variables these included the exponential, Erlang, gamma, loglogistic, lognormal, normal, Pearson VI, Pearson V and Weibull distributions. In the case of discrete variables these were the geometric, hypergeometric, Poisson, binomial and negative binomial distributions. Finally, each theoretical distribution was compared to the original data and tested for goodness-of-fit. The Kolmogorov-Smirnov goodness-of-fit test was selected for use with continuous data as its results are not dependent upon the number of intervals in which the data are presented. However, there are practical problems associated with applying the Kolmogorov-Smirnov test to discrete data (Law and Kelton, 1991). The chi square test was therefore used with discrete data and the number of histogram intervals (N) determined using Scott's Normal Approximation (anonymous, 1996), where n is the number of data points:

$$N = (4n)^{2/5}$$

It is generally considered that a p value greater than 0.05 represents an adequate goodness-of-fit (Oakshott, 1997), but visual inspection of the distribution's general shape and extreme values are also important. In the present study, the final choice of each

distribution was therefore made using the results of the goodness-of-fit tests, visual inspection and *a priori* knowledge about the variable concerned.

In remainder of this chapter, the data collection relating to each objective will be considered in turn. In each case, the appropriate methodology will be discussed before giving any relevant definitions. The specific methods used for data collection and analysis will then be given before reporting the results and how the data were represented in the model. The results presented relate only to drugs prescribed for regular administration via the oral, inhaled, ocular, aural and nasal routes as it was these that were included in the model.

4.5 Times and frequencies of medication order writing and discontinuation

Data concerning the times and frequencies of medication order writing and discontinuation were required so that these processes could be represented within the model. The preliminary study described in section 3.6 suggested that the times at which medication orders are written may significantly affect the U-MAE rate; it was therefore considered important that these data were determined as accurately as possible.

4.5.1 Methodology

Previous studies indicate that the frequencies with which medication orders are written vary according to hospital ward, time of day and day of week (Bottomley, 1993; Hartland, 1996; Slee and Farrar, 1998). Data specific to the study wards were therefore required. An observational method, based on that developed by Bottomley (1993) was selected for use; alternatives such as self reporting by medical staff were considered potentially unreliable.

4.5.2 Definitions

A *prescription event* was defined as any new medication order, discontinuation or

medication order change. A *new medication order* was defined as any medication order added to a patient's drug chart that would necessitate the administration of an additional product to those already prescribed. A *discontinuation* referred to the discontinuation of an existing medication order. Where a valid period was specified for a medication order, the medication order was considered to have been discontinued immediately after the last dose scheduled. A *medication order change* was defined as a change to an existing medication order that would not necessitate the administration of a different product from those already prescribed. Changing the times of administration or the number of daily doses are examples of medication order changes. Where an existing medication order was changed so as to require the administration of a new drug or a new dosage form, this was considered to be a discontinuation followed by a new medication order, even if the same section of the drug chart was used. However, changing the prescribed dose of warfarin was considered to be a medication order change rather than a new medication order. This was because all three strengths of warfarin tablet are routinely dispensed to any patients prescribed warfarin in the study hospital and doses are usually prescribed daily.

4.5.3 Data collection methods

Data were collected for 14 consecutive days, from Monday 27 October to Sunday 9 November 1997 inclusive. At the beginning of this period, all existing regularly scheduled medication orders on each study ward were marked in pencil. Two hours later, the researcher visited each ward again to examine each drug chart and record any prescription events that had occurred during the preceding time period. Each new prescription event was then marked. This process was repeated every two hours from 8 am to 8 pm throughout the study period. Where prescription events occurred between 8 pm and 8 am, the date indicated on the drug chart or in the patient's medical notes was used to determine whether the event had occurred before or after midnight.

Records were kept for each patient; these included the times and dates of admission and discharge as well as the following information for each prescription event identified: time period in which the event occurred, type of prescription event (new medication order,

discontinuation or change), drug, dose, frequency, times at which doses were scheduled to be administered and route of administration. The data collection form used is shown in Appendix 5. The midnight bed occupancy was also recorded for each study day.

4.5.4 Data analysis

Each new medication order was classified as being written either on admission or during the remainder of a patient's stay. The number of medication orders written for each new admission was determined and the theoretical distribution that best represented these data selected for each ward. Medication orders written subsequent to admission were classified according to time of day and day of week, and the mean number of medication orders written per patient per hour calculated for each hour of the week. Discontinuations were classified according to the drug rounds between which they occurred.

4.5.5 Results

4.5.5.1 Overview

Surgical ward

A total of 56 patients were present on the 28-bed surgical ward at some point during the fourteen-day study period. The mean midnight bed occupancy was 83% (range 75% to 100%). There were 20 admissions during the first study week and 18 during the second. At the beginning of the data collection period, there were 133 active medication orders for 26 patients (mean 5.1 per patient).

Medical ward

In total, 38 patients were present on the 16-bed medical ward at some point during the study period. The mean midnight bed occupancy was 93% (range 79% to 100%). There were 17 admissions during the first week and 11 during the second. At the beginning of the data collection period, there were 103 active medication orders for 15 patients (mean 6.9 per patient).

The prescription events identified on each ward are summarised in figures 4.1 and 4.2.

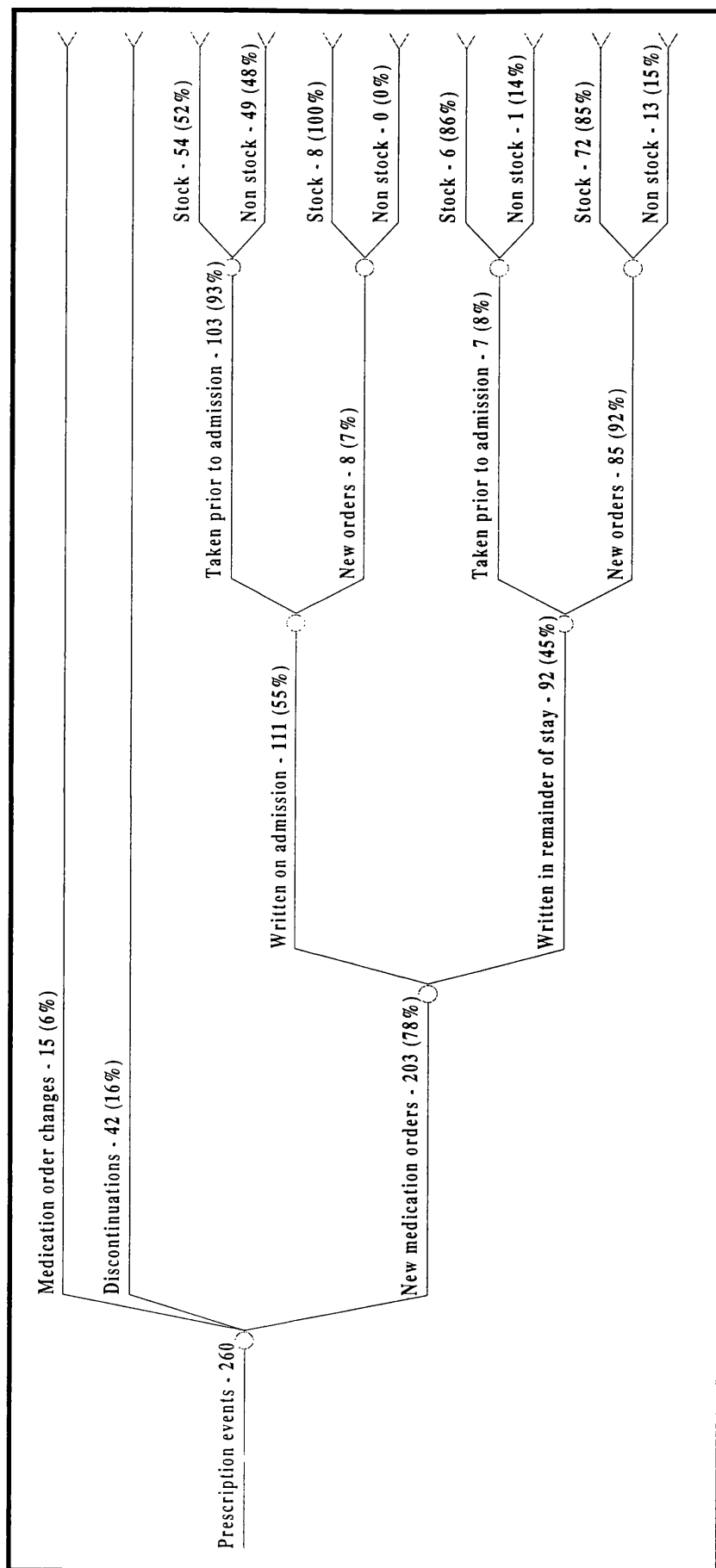


Figure 4.1 Prescription events identified on the surgical ward.

Percentages are calculated for each node of the tree.

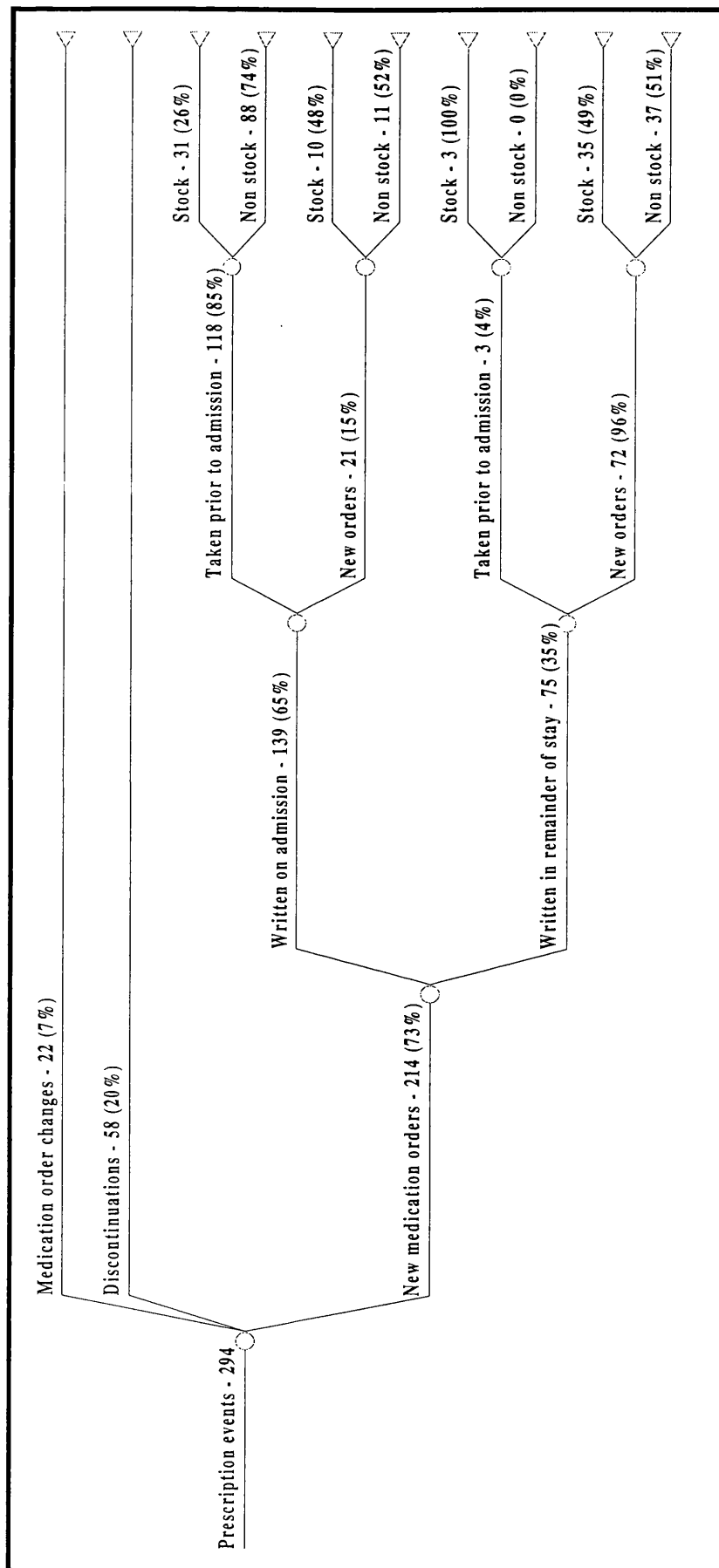


Figure 4.2 Prescription events identified on the medical ward.

Percentages are calculated for each node of the tree.

4.5.5.2 *New medication orders written on admission*

Surgical ward

A total of 111 medication orders were written on admission for the 38 patients admitted to the surgical ward (55% of all new medication orders; mean of 2.9 medication orders per patient admitted). The theoretical distribution that best represented the number of medication orders written for each newly admitted patient was the negative binomial (3, 0.51) distribution ($p = 0.61$; chi square test), as shown in figure 4.3.

Medical ward

A total of 139 medication orders were written for the 28 patients admitted to the medical ward (65% of all new medication orders; mean 5.0 per patient). The most appropriate theoretical distribution was the negative binomial (4, 0.45) distribution ($p = 0.18$; chi square test) as shown in figure 4.4.

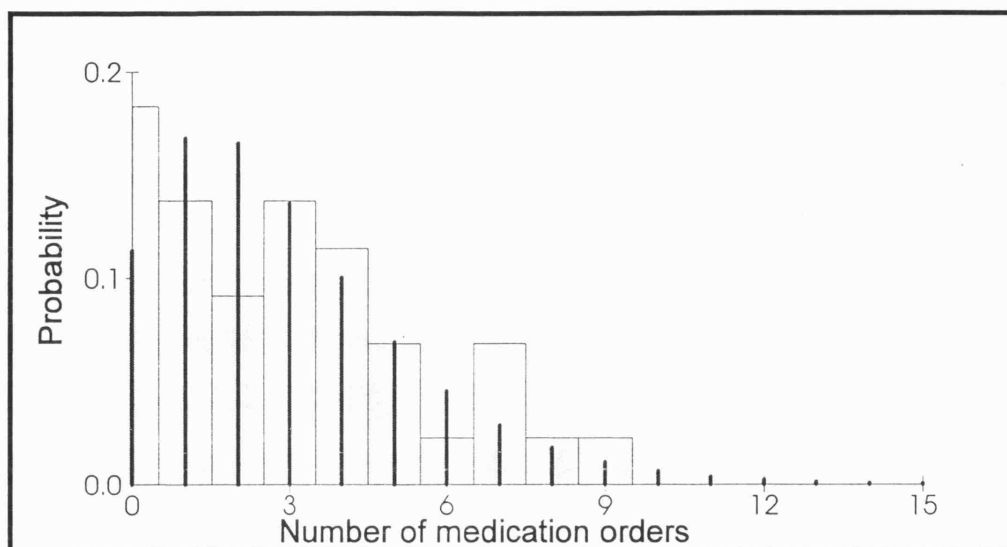


Figure 4.3 Number of medication orders written on admission for each patient admitted to the surgical ward (wide grey bars; $n = 38$ patients), compared to the negative binomial (3, 0.51) distribution (black lines).

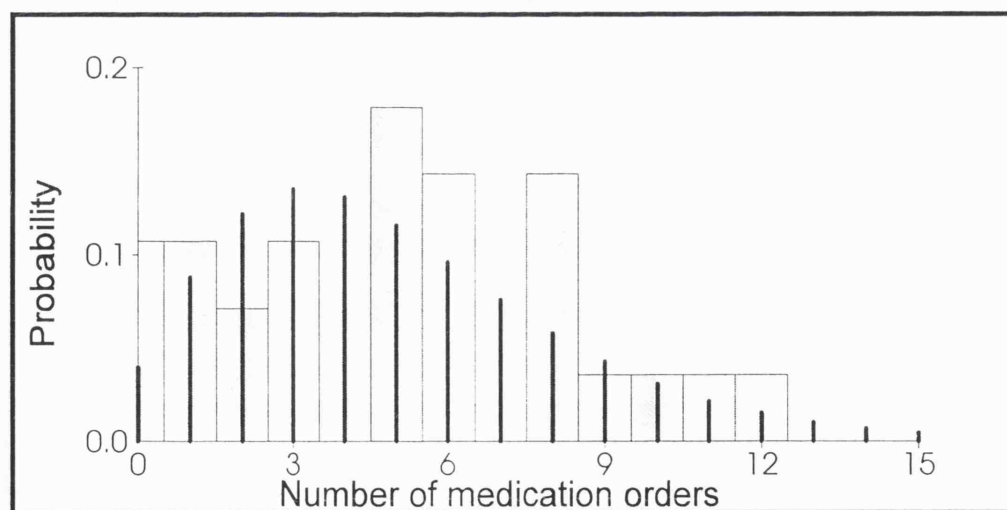


Figure 4.4 Number of medication orders written on admission for each patient admitted to the medical ward (wide grey bars; $n = 28$ patients), compared to the negative binomial (4, 0.45) distribution (black lines).

4.5.5.3 New medication orders written subsequent to admission

Surgical ward

A total of 92 medication orders were written subsequent to admission, of which 91 (99%) were written between Monday and Friday (figure 4.5). The numbers of medication orders written each weekday were not equal ($p = 0.02$; chi square test). However, to avoid additional complexity in the model it was assumed that the numbers written each weekday were equal, with a mean of 9.1 per day. This simplification was considered unlikely to affect the model's results as pharmacy services are the same from Mondays to Fridays. It was also assumed that on average, one medication order was written each weekend. The time of medication order writing was known for 80 (88%) of the 91 weekday medication orders (figure 4.6). The remaining eleven were written while patients were in the operating theatre or during a ward round to which the researcher did not have access. The sample was too small to identify any interaction between time of day and day of week. The one medication order written during a weekend was written between 8 am and 10 am on a Saturday morning.

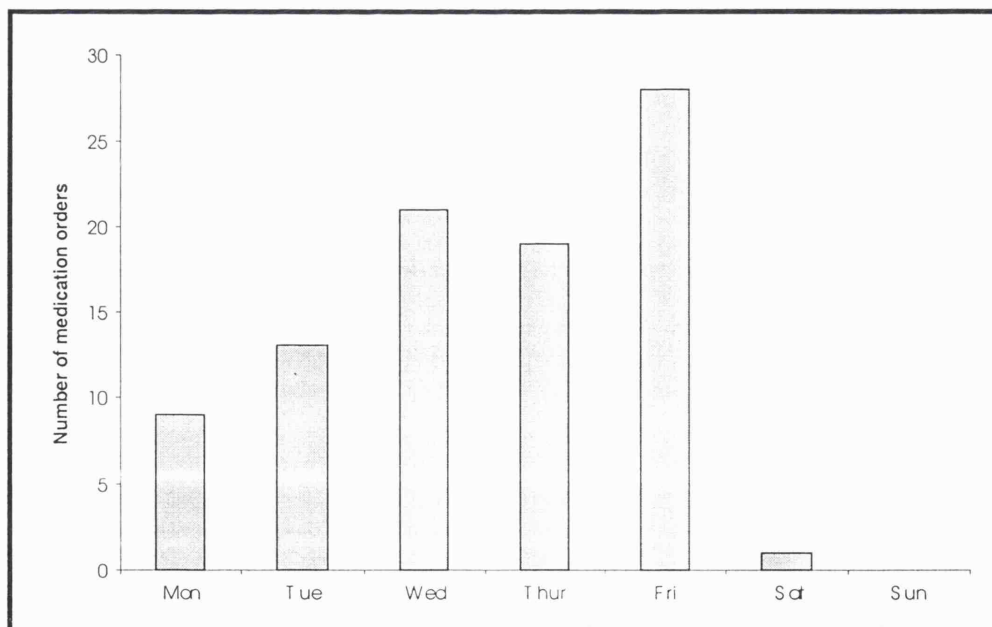


Figure 4.5 Medication orders written subsequent to admission during each day of the week on the surgical ward (n = 92 medication orders written during a fourteen-day period).

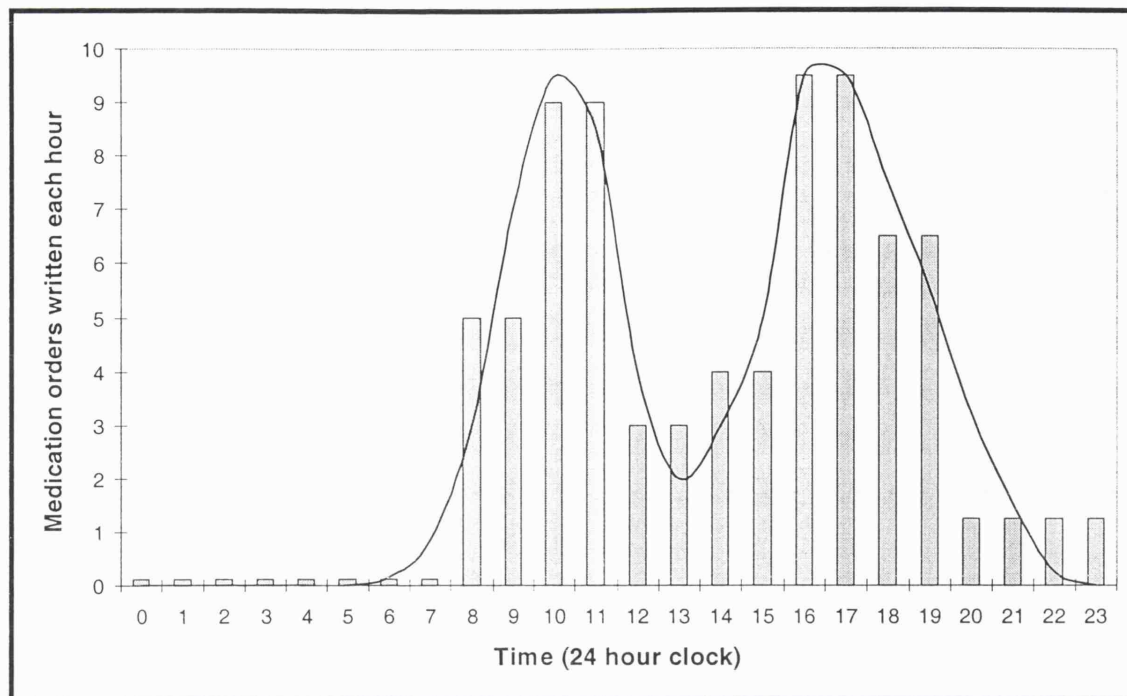


Figure 4.6 Times at which medication orders were written on the surgical ward (grey bars; $n = 80$ medication orders written during a fourteen-day period). These data refer to weekday medication orders that were written subsequent to the patient's admission; the black line shows the empirical distribution used to represent these data in the model.

These data were used to produce an empirical distribution describing the times at which weekday medication orders were written. Although the weekend medication order observed was written between 8 am and 10 am, it was assumed that weekend medication orders could be prescribed at any time between 8 am and noon on Saturdays or Sundays as these are the times between which weekend ward rounds take place on the surgical ward. The mean number of medication orders written per patient per hour was calculated for each hour of the week; these data are included in Appendix 6.

Medical ward

There were 75 medication orders written subsequent to admission during the study period. The days and time periods during which these medication orders were written are shown in figures 4.7 and 4.8. Of the eight medication orders written during the weekends, three were written between 8 am and 10 am, two between 10 am and noon and two between 2 pm and 4 pm. The time period during which the eighth was written was unknown.

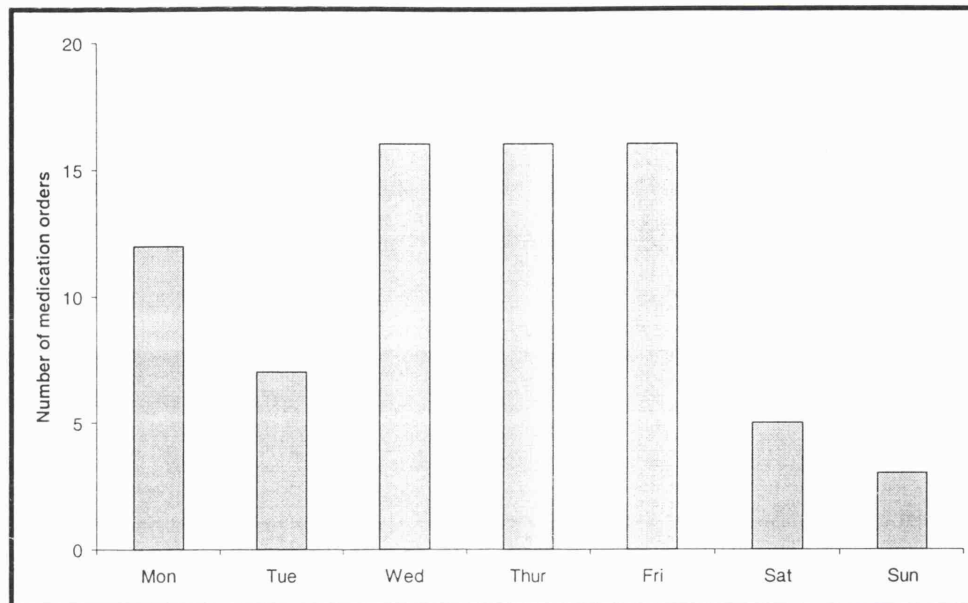


Figure 4.7 Medication orders written subsequent to admission during each day of the week on the medical ward ($n = 75$ medication orders written during a fourteen-day period).

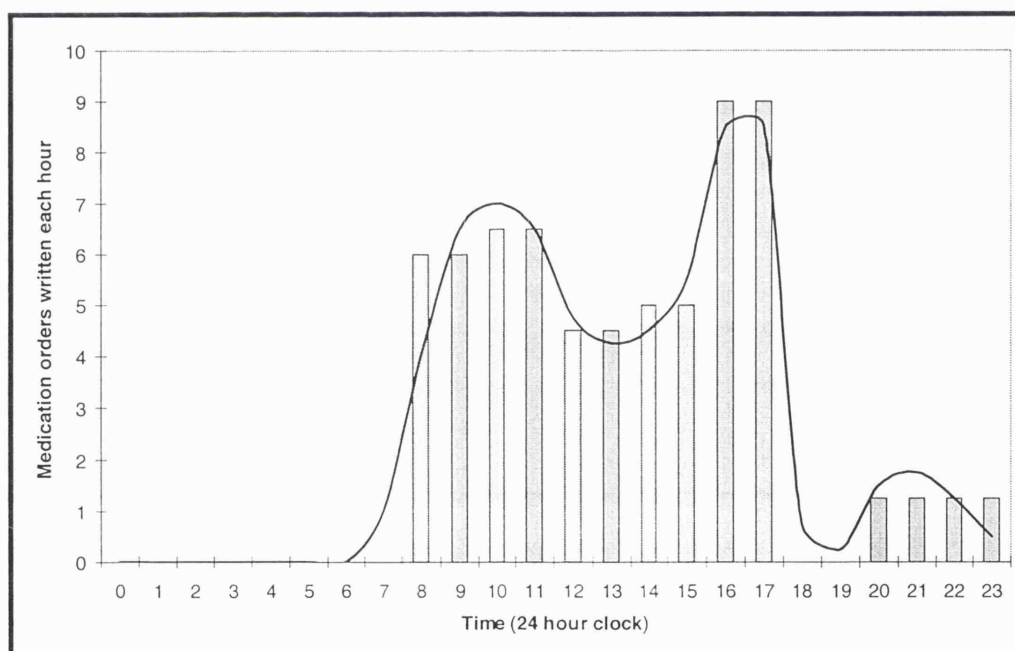


Figure 4.8 Times at which medication orders were written on the medical ward (grey bars; $n = 67$ medication orders written during a fourteen-day period).

These data refer to weekday medication orders that were written subsequent to the patient's admission; the black line shows the empirical distribution used to represent these data in the model.

There were no significant differences amongst weekdays regarding the numbers of medication orders written ($p = 0.32$; chi square test), and it was therefore assumed that a mean of 6.7 were written each weekday. It was assumed that medication orders written at weekends could be written between 8 am and 4 pm on either Saturdays or Sundays. The data shown in figures 4.7 and 4.8 were used to calculate the number of medication orders written per patient per hour for each hour of the week (Appendix 6).

4.5.5.4 Discontinuation of medication orders

Surgical ward

During the fourteen-day study period, 42 medication orders were discontinued. This is equivalent to approximately 0.12 per patient day. Ten (24%) of the 42 discontinuations took place between 8 am and noon, 23 (55%) between noon and 6 pm and 9 (21%) between 6 pm and 8 am.

Medical ward

There were 58 discontinuations during the study period, equivalent to about 0.28 per patient day. The time at which five of these took place was unknown. Of the remaining 53 discontinuations, 32 (60%) took place between 8 am and noon; 17 (32%) between noon and 6 pm and 4 (8%) between 6 pm and 8 am.

4.6 Characteristics of the drugs prescribed

4.6.1 Methodology

Characteristics of interest for each new medication order included whether the drug concerned was ward stock, whether it was taken by the patient prior to their admission and the dose regime prescribed. These data were required for both medication orders written on admission and those written subsequently, so that these could be modelled separately. It was therefore decided to collect these data during the fourteen-day observational study described in section 4.5.

4.6.2 Definitions

A *stock* drug was defined as any drug that could be administered using a preparation listed on the ward's stock list (October 1997). A drug taken *prior to admission* was defined as a preparation that a patient was taking immediately prior to admission to the study ward, according to his or her medical notes. A drug's *dose regime* was the number of daily doses and the times for which they were scheduled.

4.6.3 Data collection methods

During the fourteen-day observational study described in section 4.5, the characteristics of each new medication order were recorded. The medical notes were used to determine whether the medication was taken by the patient concerned prior to his or her admission, and the ward stock list used to determine whether or not it was ward stock.

4.6.4 Data analysis

The proportions of medication orders that were for drugs taken prior to admission, the proportions that were for stock drugs and the proportions of each dose regime were calculated for each ward. The characteristics of the medication orders written on admission were considered separately to those written during the remainder of a patient's stay.

4.6.5 Results

4.6.5.1 *Drugs taken prior to admission*

Surgical ward

Overall, 54% of the 203 new medication orders were for preparations that patients were taking prior to their admission (figure 4.1). Of the 111 medication orders written at admission, 93% were for preparations taken by patients prior to their admission (95% confidence interval 88% to 98%). However, of the 92 medication orders written subsequently, only 8% had been taken prior to admission (95% confidence interval 2% to 14%).

Medical ward

Overall, 57% of the 214 new medication orders were for drugs taken prior to the patient's admission (figure 4.2). Of the 139 medication orders written at admission, 85% were for preparations taken by the patient prior to their admission (95% confidence interval 79% to 91%). Of the 75 written subsequently, only 4% were taken prior to admission (95% confidence interval 0% to 8%).

4.6.5.2 Stock drugs

Surgical ward

Overall, the proportion of new medication orders that were for stock drugs was 69% (95% confidence interval 63% to 75%). However, the proportion of stock drugs varied depending on whether medication orders were written at admission or subsequently and whether or not they were for preparations that patients had been taking prior to their admission (figure 4.1).

Medical ward

Only 37% of all new medication orders were for stock drugs (95% confidence interval 31% to 43%). Again, the percentages varied depending on whether medication orders were written at admission or subsequently, and whether or not they were for preparations that the patient had been taken prior to admission (figure 4.2). However, it was observed that many items on the medical ward were dispensed as 'temporary stock' or had been dispensed for previously discharged patients. Although not on the official stock list, these items were therefore available on the ward. If these temporary stock items are included, 71% of all medication orders can be considered ward stock (95% confidence interval 65% to 77%). Of those medication orders written on admission, 70% could be considered stock (95% confidence interval 62% to 78%); this figure was 75% for those prescribed subsequently (95% confidence interval 65% to 85%). These revised figures were used in the model to represent the percentages of medication orders on the medical ward that were for stock drugs.

4.6.5.3 Dose regimes

The frequencies at which drugs were prescribed to be administered were different on each

study ward ($p < 0.001$; chi square test), as shown in table 4.1. The higher proportion of drugs administered three times daily on the medical ward was mainly due to the prescription of Calcichew tablets with meals for patients with renal failure. The higher proportion of four times daily doses on the surgical ward can be explained by the extensive use of oral antibiotics in surgical patients, many of which are administered four times a day.

Frequency	Surgical ward	Medical ward
Once daily	93 (46%)	106 (50%)
Twice daily	39 (19%)	39 (18%)
Three times daily	24 (12%)	47 (22%)
Four times daily	45 (22%)	20 (9%)
Other	2 (1%)	2 (1%)
Total	203 (100%)	214 (100%)

Table 4.1 Dose regimes of new medication orders written during the study period.

Because very few medication orders were prescribed to be administered more frequently than four times a day or less frequently than once a day, it was decided to assume that only one, two, three and four daily doses were possible in the model.

Surgical ward

Significant differences existed in the dose regimes prescribed for drugs written on admission versus those written subsequently ($p < 0.001$; chi square test), for stock versus non-stock drugs ($p = 0.003$; chi square test) and for drugs taken prior to admission versus those that were not ($p < 0.001$; chi square test). However, the samples were too small to allow a multivariate analysis to be carried out. Since there was no *a priori* reason to suggest the presence of interactions, it was assumed that none existed. Probabilities of each dose regime were calculated for each of the eight types of medication order; these are shown in Appendix 6.

Medical ward

Similarly, there was a significant difference in the dose regimes of drugs taken prior to the

patient's admission compared with those that were not ($p < 0.001$; chi square test). However, the differences between medication orders written on admission and those written subsequently, and between stock and non-stock drugs failed to reach statistical significance ($p = 0.07$ and 0.05 respectively; chi square tests). The calculated probabilities of each dose regime for each type of medication order are shown in Appendix 6.

4.6.5.4 Times of administration

Table 4.2 shows the times at which doses were scheduled to be administered on each ward.

Number of daily doses	Number of doses scheduled for the time indicated (percentage) *							
	Surgical ward				Medical ward			
	1	2	3	4	1	2	3	4
6 am or 8 am[†]	66 (71%)	39 (100%)	24 (100%)	45 (100%)	89 (84%)	39 (100%)	47 (100%)	20 (100%)
noon or 2 pm[†]	1 (1%)	0	24 (100%)	45 (100%)	0	2 (5%)	47 (100%)	20 (100%)
6 pm	8 (9%)	31 (79%)	4 (17%)	45 (100%)	4 (4%)	19 (49%)	24 (51%)	20 (100%)
10 pm	18 (19%)	8 (21%)	20 (83%)	45 (100%)	13 (12%)	18 (46%)	23 (49%)	20 (100%)
TOTAL	93	39	24	45	106	39	47	20

Table 4.2 Times at which doses were scheduled to be administered.

[†] On each ward, all 8 am doses were given at 6 am and all 2 pm doses at noon. Drugs scheduled for these times were therefore considered together.

* percentages refer to those medication orders of the dose regime stated that had a dose scheduled for this time.

In order to represent these data in the model, it was assumed that:

1. all once daily doses are administered during the morning drug round
2. all twice daily doses are administered during the morning drug round and at 6 pm
3. all three times daily doses are administered during the morning round, during the lunchtime round and at 10pm

4. all four times daily doses are administered during the morning, lunchtime, 6 pm and 10 pm rounds.

It was also assumed that there were no interactions between the times of administration and whether or not drugs were stock, or whether or not drugs were taken prior to the patient's admission.

4.7 Times and frequencies of patient admissions and times of discharge

4.7.1 Methodology

Information was required concerning the frequency and times at which patients are admitted to each study ward. Times of discharge were also of interest. Discussions with staff in the hospital information department revealed that computerised hospital activity data existed for the previous two years, and that these records included the dates and times of each patient's admission and discharge for each ward. However, following discussions with ward staff, it was concluded that the times of admission and discharge were unlikely to be accurate because they were entered into the hospital information system retrospectively. Dates were considered to be correct, but the times recorded were more likely to reflect the times of data entry than the times of admission or discharge. It was therefore decided to use the information department's data to study the frequencies and days of admission, but to obtain information on the times of admission and discharge from the data gathered during the fourteen-day observational study described in section 4.5.

4.7.2 Definitions

Ward admission was defined as the arrival of a patient on the study ward, whether from their home, another ward or department in the hospital or from another hospital. For the purposes of this study, the *time* of ward admission was considered to be the time at which the patient's drug chart was written.

Ward discharge was defined as the departure of a patient from a study ward, whether to their home, another ward or hospital, or to the mortuary. For the purposes of this study, the *time* of discharge was considered to be the time at which the patient physically departed from the ward. The transfer of a patient to the renal dialysis unit was not considered to be a discharge, as patients generally return to their original ward later the same day. Any medication due while a patient is in the renal dialysis unit is generally given on their return to the ward.

4.7.3 Data collection methods

4.7.3.1 Admission rates and days of admission

The following information was obtained from the hospital information department for each patient admitted to the surgical ward during the preceding twelve months and each patient admitted to the medical ward in the ten months since its opening:

1. Patient identification number
2. Gender
3. Type of admission
4. Date and source of ward admission
5. Date of ward discharge

Where patients were admitted to a study ward more than once during the same hospital admission, these were considered as separate ward admissions. The percentage bed occupancy was also determined for each ward.

4.7.3.2 Times of admission and times of discharge

The time period in which each admission and discharge took place was recorded during the fourteen-day observational study described in section 4.5.

4.7.4 Data analysis

4.7.4.1 Admission rates and days of admission

The week in which the medical ward first opened was excluded from the analysis as this was considered unlikely to represent typical admission patterns.

For each ward, the numbers of admissions during each week and each month were calculated and chi square tests used to determine whether any significant differences existed amongst weeks or months. Histograms of the numbers of patients admitted on each day of the week were also produced. It was anticipated that on the surgical ward, the mean number of daily admissions would be similar for Sundays to Thursdays, but that Fridays and Saturdays would have lower admission rates; this was because most elective surgery takes place between Monday and Friday. On the medical ward, it was anticipated that mean admission rates would be lower on Saturdays and Sundays than during weekdays, but that weekdays would have similar mean admission rates. Chi square tests were used to determine whether these assumptions were appropriate.

4.7.4.2 Times of admission and times of discharge

The data collected during the fourteen-day observational study were used to identify the time intervals in which admissions and discharges occurred. For each ward, the mean number of patients admitted during each hour of the week was estimated using the mean number of weekly admissions, the proportion of patients admitted on each day of the week and the proportion of patients admitted during each time period. It was assumed that there was no interaction between time of day and day of week.

4.7.5 Results

4.7.5.1 Admission rates and days of admission

Table 4.3 summarises the patients admitted to each ward.

	Surgical ward (28 beds) 1 Nov '96 to 31 Oct '97	Medical ward (16 beds) 1 Jan '97 to 31 Oct '97
Ward admissions	1059	586
Percentage males *	61.9%	56.7%
Type of admission †		
Elective	459 (43.3%)	231 (39.4%)
Emergency	461 (43.5%)	178 (30.4%)
Ward transfer	103 (9.7%)	121 (20.6%)
Hospital transfer	36 (3.4%)	50 (8.5%)
Direct access	0 (0%)	6 (1.0%)
Source of admission †		
Accident & Emergency	395 (37.3%)	64 (10.9%)
Home	486 (45.9%)	290 (49.5%)
Outpatient clinic	39 (3.7%)	61 (10.4%)
Other ward	103 (9.7%)	121 (20.6%)
Other hospitals	36 (3.4%)	50 (8.5%)
Mean ward stay ‡	9.2 nights	6.7 nights
Mean bed occupancy †	91%	84%

Table 4.3 Details of ward admissions.

* Difference between wards significant ($p = 0.04$; chi square test).

† Difference between wards significant ($p < 0.001$; chi square test).

‡ Difference between wards significant ($p < 0.001$; Mann-Whitney test).

Surgical ward

A total of 828 patients had been admitted on at least one occasion between 1 November 1996 and 31 October 1997. These represented 956 hospital admissions and 1059 ward admissions. Numbers of admissions were equally distributed by week and by month ($p > 0.05$; chi square test); the mean number of weekly admissions was 19.9. More patients were admitted on each day from Sunday to Thursday than on Fridays and Saturdays ($p < 0.001$; chi square test), as shown in figure 4.9. Fridays and Saturdays were also significantly different from each other ($p < 0.01$; chi square test). There were no significant differences in the numbers of patients admitted each day from Sunday to Thursday ($p = 0.50$; chi square test).

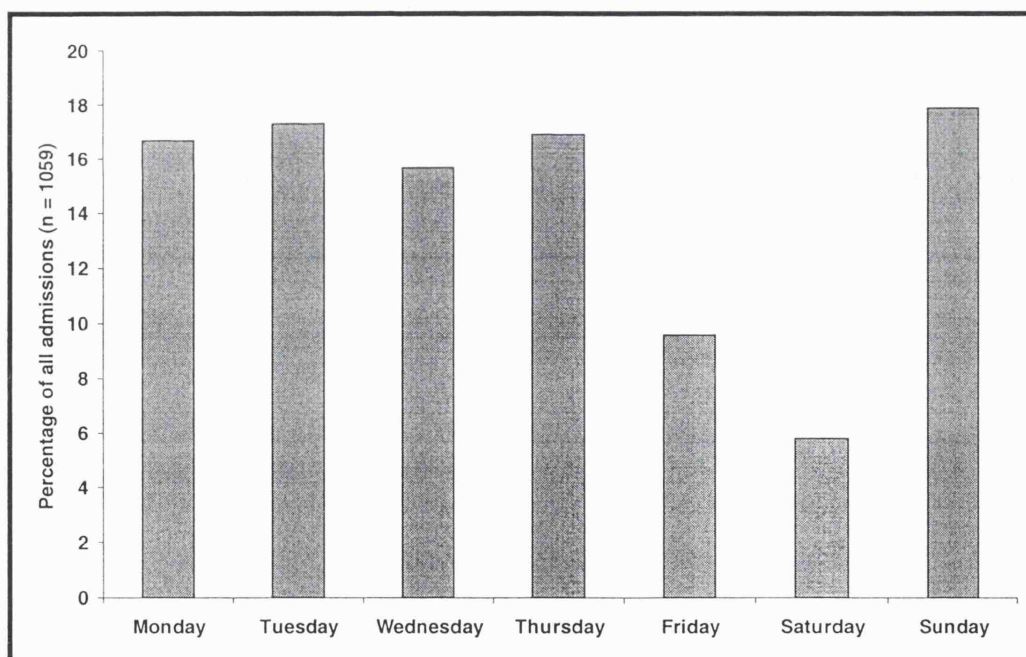


Figure 4.9 Days of the week on which patients were admitted to the surgical ward.

Medical ward

Between 1 January 1996 and 31 October 1997, 333 patients had been admitted on at least one occasion to the medical ward. These represented a total of 545 hospital admissions and 586 ward admissions. Numbers of admissions were equally distributed by week and by month ($p > 0.05$; chi square test); the mean number of weekly admissions was 13.2. More patients were admitted each day during weekdays than during the weekend ($p < 0.001$; chi square test), as shown in figure 4.10. Surprisingly however, the numbers of patients admitted on each day from Monday to Friday were not equal ($p = 0.02$; chi square test). However, to avoid additional complexity during model construction, it was assumed that numbers of admissions were equal each weekday. This was considered appropriate as pharmacy services are identical between Mondays and Fridays. There was no significant difference between Saturdays and Sundays ($p > 0.05$; chi square test).

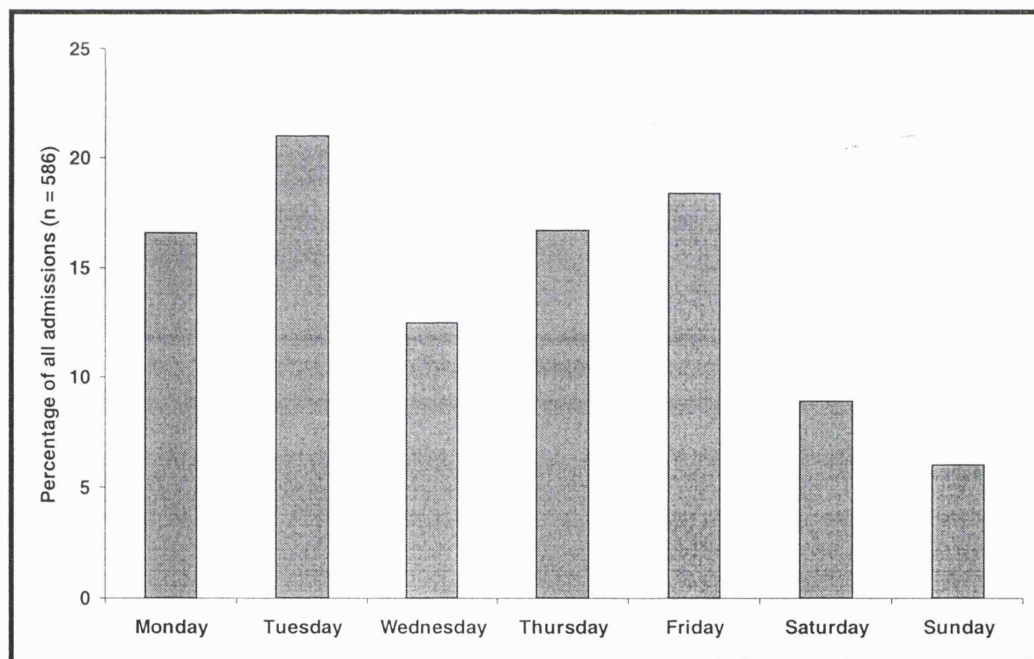


Figure 4.10 Days of the week on which patients were admitted to the medical ward.

4.7.5.2 Times of admission

Surgical ward

During the fourteen-day observational study, admission times were recorded for 36 of the 38 patients admitted (95%). The majority of admissions took place between 2pm and midnight (figure 4.11). These data and the data describing the number of patients admitted during each day of the week were used to estimate the mean number of patients admitted during each hour of the week. These data are included in Appendix 6.

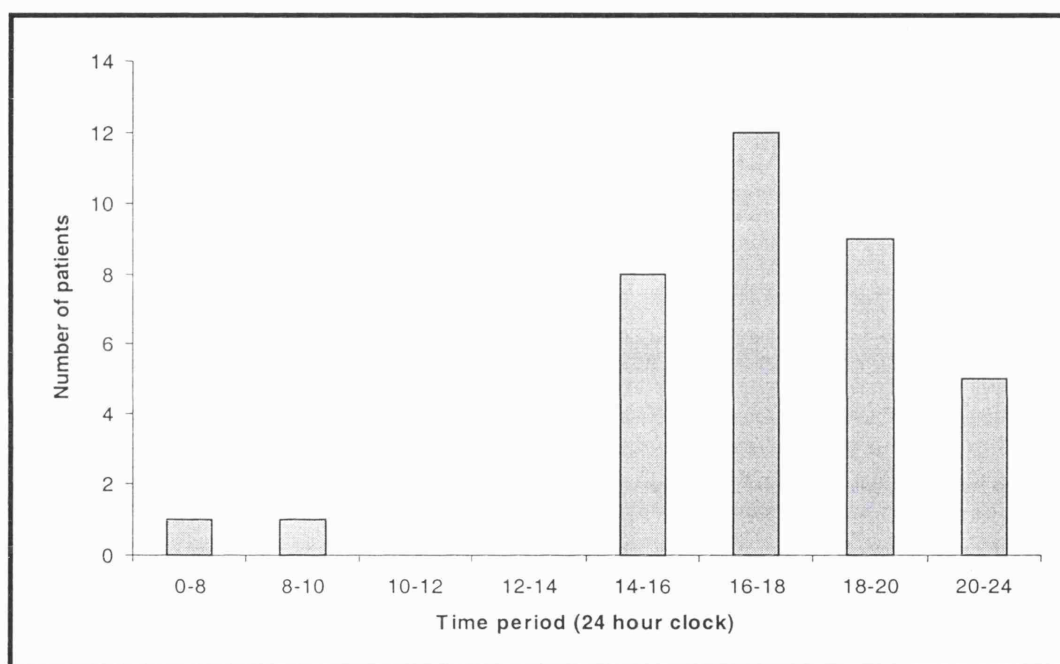


Figure 4.11 Time periods in which patients were admitted to the surgical ward during the two week observational study (n = 36 patients).

Medical ward

On the medical ward, times of admission were determined for 26 of the 28 patients admitted (93%), these are shown in figure 4.12. Mean inter-arrival times for each hour of the week were calculated as for the surgical ward; these are shown in Appendix 6.

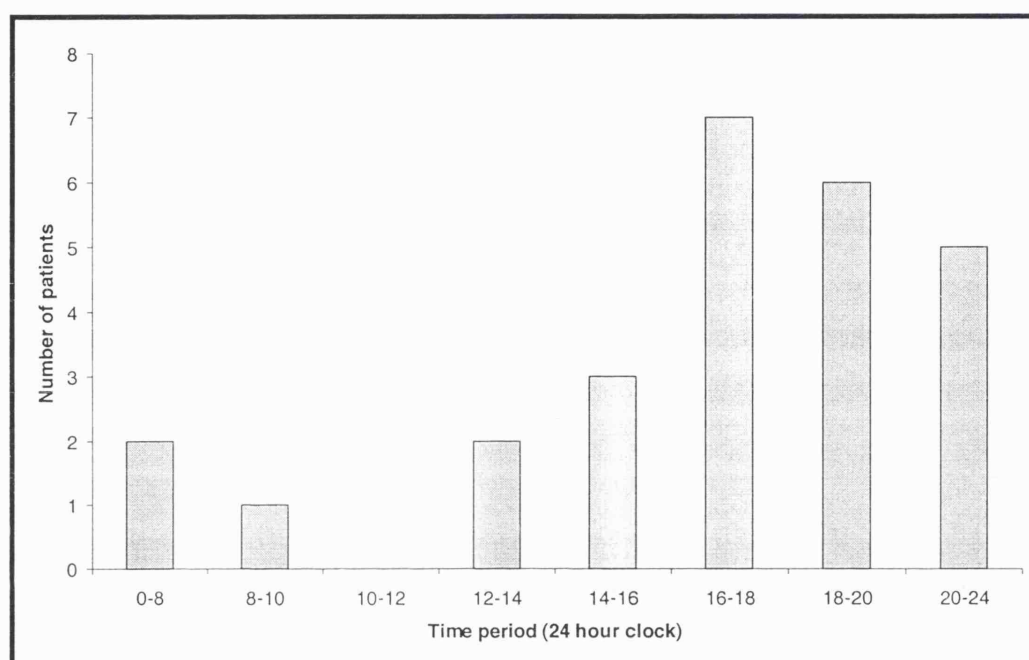


Figure 4.12 Time periods in which patients were admitted to the medical ward during the two-week observational study (n = 26 patients).

4.7.5.3 Times of discharge

Surgical ward

Times of discharge were determined for 30 of the 31 patients (97%) discharged from the surgical ward during the fourteen-day study period. Of these, 15 (50%) were discharged between 8 am and noon; 13 (43%) between noon and 6 pm and the remaining 2 (7%) between 6 pm and midnight. None were discharged between midnight and 8 am.

Medical ward

Of the 23 patients discharged from the medical ward, 1 (4%) was discharged between 8 am and noon, 19 (83%) between noon and 6 pm and 3 (13%) between 6 pm and midnight.

4.8 Ward lengths of stay

4.8.1 Methodology

Although the hospital information department could provide details of hospital lengths of stay, records were not kept for ward lengths of stay. However, the dates of ward admission and discharge were recorded for each patient, from which the ward lengths of stay could be calculated.

4.8.2 Definition

Ward length of stay was defined as the number of nights spent on a study ward between ward admission and ward discharge. Where a patient had two or more admissions to the study ward within one hospital admission, the duration of each was considered separately.

4.8.3 Data collection methods

The hospital information department was asked to provide dates of ward admission and discharge for each patient admitted to the surgical ward during the preceding twelve months and each patient admitted to the medical ward in the ten months since its opening.

4.8.4 Data analysis

The ward length of stay was calculated for each patient. Histograms of ward length of stay were produced for each ward and the most appropriate theoretical distributions selected.

4.8.5 Results

4.8.5.1 *Ward lengths of stay*

Discrete distributions, describing the length of stay in nights, were tested for goodness-of-fit but all those tested in the model were found to grossly underestimate bed occupancy.

Attempts were then made to use empirical distributions, but these also proved inadequate. It was therefore decided to consider the use of continuous distributions. None of the continuous distributions tested fitted the length of stay data for either ward ($p < 0.01$; Kolmogorov-Smirnov tests), but exponential distributions gave satisfactory mean lengths of stay and percentage bed occupancies when tested in the model. It was therefore decided to represent the distributions of ward lengths of stay using exponential distributions.

Surgical ward

An exponential distribution with a mean of 9.2 nights (221 hours) was selected (figure 4.13).

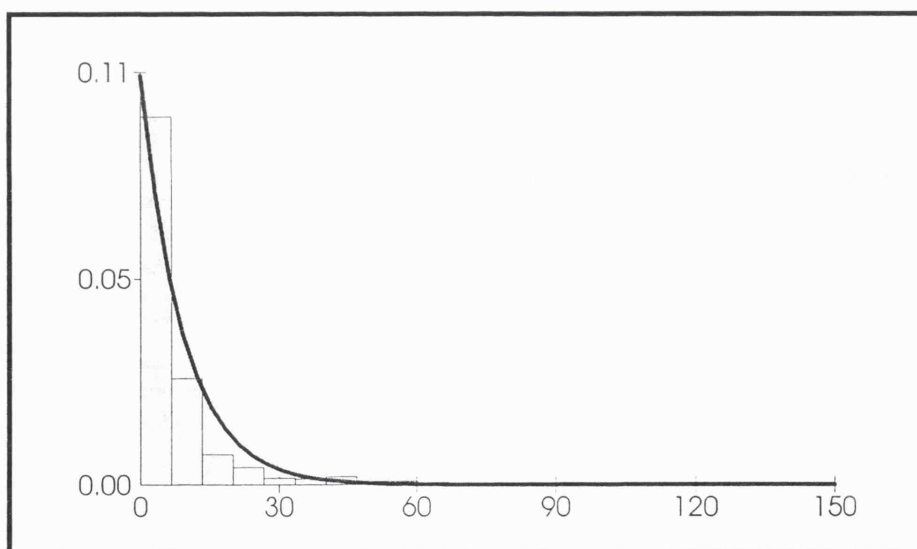


Figure 4.13 Surgical ward length of stay in nights (grey bars, $n = 1059$ ward admissions) compared to the exponential (9.2) distribution (black line).

Lengths of stay of up to 350 nights also existed; for clarity these are not shown in the figure.

Medical ward

An exponential distribution with a mean of 6.7 nights (161 hours) was selected (figure 4.14).

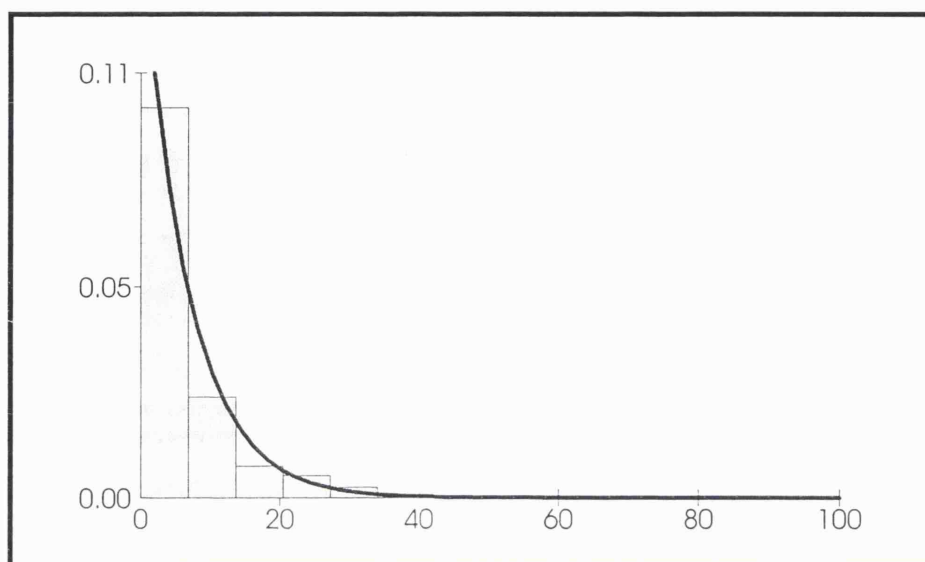


Figure 4.14 Medical ward length of stay in nights (grey bars, $n = 586$ ward admissions) compared to the exponential (6.7) distribution (black line).

Lengths of stay of up to 150 nights also existed; for clarity these are not shown in the figure.

4.9 Times and durations of pharmacists' ward visits.

4.9.1 Methodology

It was decided to ask the ward pharmacists to record the data required. Although observation was considered potentially more accurate, it was considered that adequate data could be obtained from pharmacists' self reporting which is much less labour-intensive.

4.9.2 Definition

The *time* of the ward pharmacist's visit was defined as the time of day at which the pharmacist arrived on the study ward. The *duration* of the ward pharmacist's visit was defined as the time elapsed between the pharmacist's arrival on the ward and the delivery of his or her ward pharmacy order forms to the pharmacy department.

4.9.3 Data collection methods

The study ward pharmacists were asked to record the time at which they arrived on the ward and the time at which they returned to the pharmacy department, every weekday morning and afternoon for three weeks.

4.9.4 Data analysis

Times of arrival on each ward were converted into decimal hours of the 12-hour clock and the duration of each visit calculated. The theoretical distributions that best represented these data were then determined.

4.9.5 Results

Each ward pharmacist recorded data for fourteen weekdays. Neither pharmacist visited additional wards during this period; times recorded therefore reflect visits to the study wards only.

4.9.5.1 Times of ward visits

The distributions chosen to describe the visit times are summarised in table 4.4 and illustrated in figure 4.15.

Time	Surgical ward		Medical ward	
	Mean	Distribution	Mean	Distribution
Morning	9.91 hrs (9.55 am)	Erlang (9.91, 197) * $p > 0.15^{\dagger}$	8.93 hrs (8.56 am)	Erlang (8.93, 650). $p > 0.15$
Afternoon	2.70 hrs (2.42 pm)	Erlang (2.70, 47) $p > 0.15$	2.46 hrs (2.27 pm)	Erlang (2.46, 45) $p > 0.15$

Table 4.4 Distributions representing times of ward pharmacists' visits.

* Parameters describing Erlang distributions give the mean and the shape parameter.

[†] p values refer to Kolmogorov-Smirnov goodness-of-fit tests.

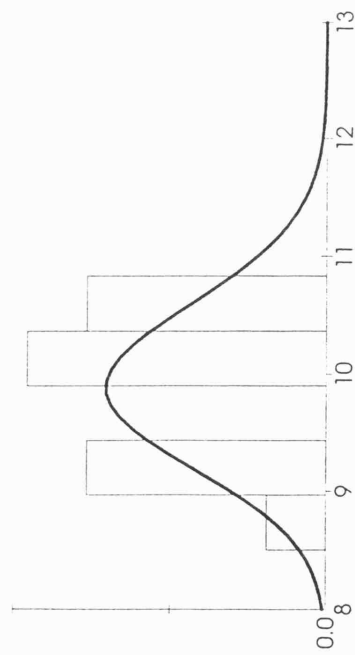
4.9.5.2 Durations of ward visits

The distributions chosen to describe the visit times are summarised in table 4.5 and illustrated in figure 4.16.

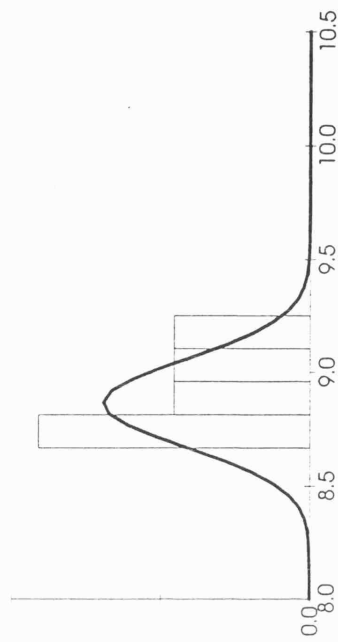
Time	Surgical ward		Medical ward	
	Mean	Distribution	Mean	Distribution
Morning	0.9 hours	Lognormal (0.90, 0.20) $p > 0.15^*$	0.55 hours	Lognormal (0.55, 0.13) $p > 0.15$
Afternoon	0.39 hours	Lognormal (0.39, 0.097) $p > 0.15$	0.33 hours	Lognormal (0.33, 0.18) $p > 0.15$

Table 4.5 Distributions representing durations of ward pharmacists' visits.

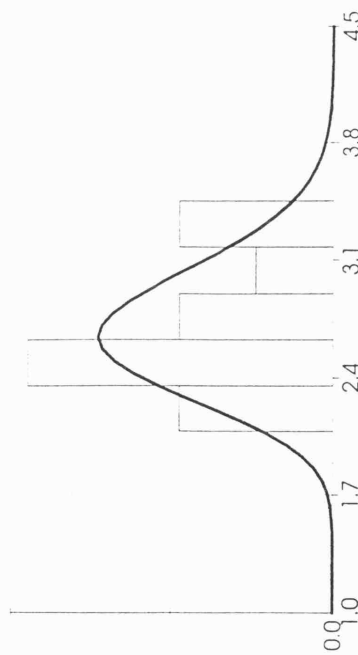
* p values refer to Kolmogorov-Smirnov goodness-of-fit tests.



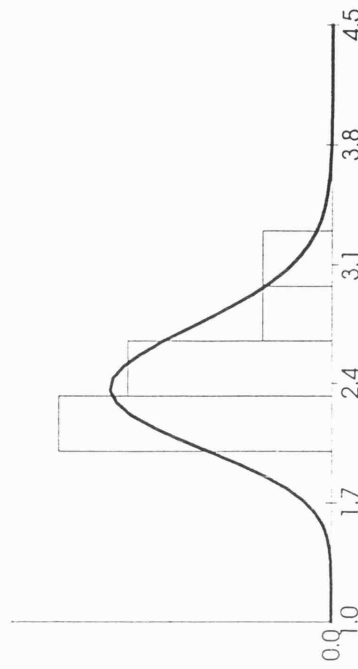
Surgical ward: times of pharmacist's morning visits (grey bars; $n = 14$) compared to Erlang (9.91, 197) distribution (black line).



Medical ward: times of pharmacist's morning visits (grey bars; $n = 14$) compared to Erlang (8.93, 650) distribution (black line).



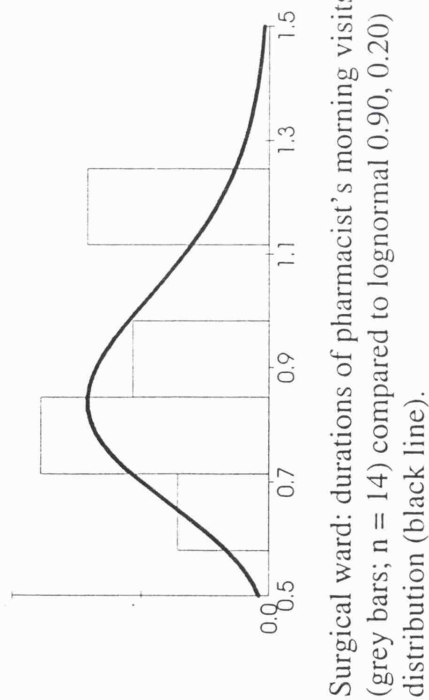
Surgical ward: times of pharmacist's afternoon visits (grey bars; $n = 14$) compared to Erlang (2.70, 47) distribution (black line).



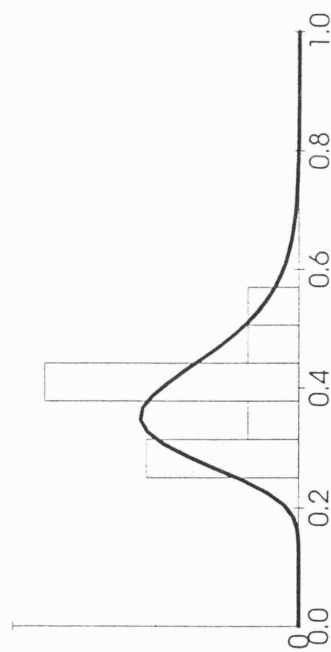
Medical ward: times of pharmacist's afternoon visits (grey bars; $n = 14$) compared to Erlang (2.46, 45) distribution (black line).

Figure 4.15 Distributions of ward pharmacists' visit times.

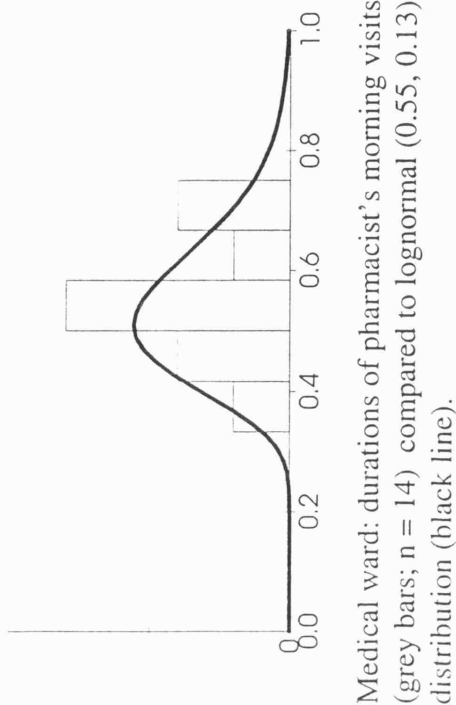
Values are in decimal hours of the 12-hour clock, y axes relate to probabilities.



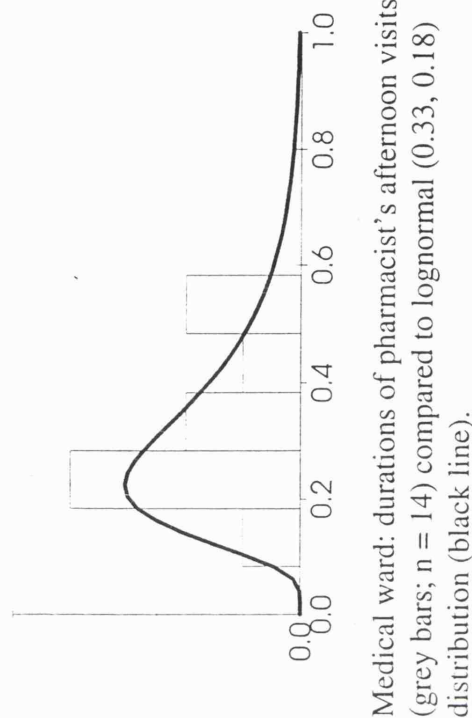
Surgical ward: durations of pharmacist's morning visits (grey bars; $n = 14$) compared to lognormal (0.90, 0.20) distribution (black line).



Surgical ward: distributions of pharmacist's afternoon visits (grey bars; $n = 18$) compared to lognormal (0.39, 0.097) distribution (black line).



Medical ward: durations of pharmacist's morning visits (grey bars; $n = 14$) compared to lognormal (0.55, 0.13) distribution (black line).



Medical ward: durations of pharmacist's afternoon visits (grey bars; $n = 14$) compared to lognormal (0.33, 0.18) distribution (black line).

Figure 4.16 Distributions of ward pharmacists' visit durations.
Values are in hours, y axes relate to probabilities.

4.10 Delays incurred during the dispensing of non-stock medication

4.10.1 Methodology

It was anticipated that dispensing times could potentially vary according to time of day, day of week and the number of items requiring dispensing on the ward pharmacy order form concerned. Since ward pharmacy order forms are prioritised according to hospital wing at the study site, it was also suspected that dispensing times might vary according to hospital wing. It was therefore considered important that the sample of dispensing times was large enough to identify such sources of variation. If dispensing times were recorded for only the two study wards, a lengthy data collection period would have been required to obtain a representative sample. It was therefore decided to collect dispensing times data for all wards in the hospital. It was considered unlikely that there would be any systematic variation amongst wards of the same hospital wing.

According to departmental procedures, pharmacists should routinely record the time at which each ward pharmacy order form arrives in the dispensary. However, the time at which dispensing is completed is not recorded. Various methods were considered for the collection of these additional data. These included the use of observation and self-reporting by pharmacy staff. Observation is likely to have higher validity than self-reporting but it is very labour intensive. It was therefore decided to ask the dispensary pharmacists to record the time at which checking procedures were completed for each ward pharmacy order form.

4.10.2 Definition

The *dispensing time* was defined as the time elapsed between the arrival of a ward pharmacy order form in the pharmacy department and the completion of dispensing and checking procedures. This time therefore includes the time spent waiting for dispensing to begin.

4.10.3 Data collection methods

The ward pharmacy order forms used in the study hospital were redesigned to include a space for the time at which all dispensing checks were completed. Ward pharmacists were given the new forms and dispensary pharmacists asked to record the information required.

4.10.4 Data analysis

The times at which ward pharmacy order forms arrived in the pharmacy department were considered according to one-hour time intervals. One-way analyses of variance (ANOVAs) were used to assess the effects of hospital wing, time of day and day of week on dispensing times. Sample sizes were too small to allow a multivariate analysis of variance to be carried out. Dispensing times for each of the two study wards were compared to those for other wards in the same wing using one-way ANOVAs, to confirm that each study ward was typical of its wing. The most appropriate theoretical distributions were then selected with which to represent dispensing times in the model.

4.10.5 Results

4.10.5.1 Overview

Data collection took place during a five-week period (12 November to 18 December 1997). Data collection was halted one week before Christmas as it was likely that workload levels and staffing patterns would be atypical after this time. During the weekdays of these five weeks, 1453 ward pharmacy order forms were processed. On only 604 order forms (42%) the time at which the order form arrived in the pharmacy department and the time at which all checks were completed were both recorded. In the majority of the remaining cases, it was the time at which dispensing was completed that was not recorded. The analyses described therefore relate to a sample of 604 ward pharmacy order forms.

4.10.5.2 Dispensing times

There were no significant differences in dispensing times for different hospital wings ($p = 0.12$; ANOVA) or days of the week ($p = 0.43$; ANOVA). However, there were significant differences in dispensing times for the different hours of the day in which ward pharmacy order forms were delivered to the pharmacy department. Mean times ranged from 21 minutes for an order form that arrived in the pharmacy department between 4 pm and 5 pm, to 1 hour 40 minutes for a form that arrived between 1 pm and 2 pm ($p < 0.001$; ANOVA). The number of items on the order form also affected dispensing times; the mean times ranged from 44 minutes for order forms with one item, to 2 hours 25 minutes for forms with 11 items ($p < 0.001$; ANOVA). There was no significant difference between the dispensing times for the surgical ward and those for other wards in the same wing ($p = 0.15$; ANOVA). However there was a significant difference between the dispensing times for the medical ward (mean 1 hour 38 minutes) and those for other wards in the same hospital wing (mean 55 minutes) ($p < 0.001$; ANOVA). The reason for this is unknown; there were no significant differences between this ward and the other wards regarding the number of items on each order form or the times at which ward pharmacy order forms were delivered to the pharmacy department.

For simplicity, it was decided to represent dispensing times in the model using a single distribution. The distribution that best represented the overall dispensing times was the lognormal (0.97, 0.95) distribution ($p = 0.03$; Kolmogorov-Smirnov test), as shown in figure 4.17. The implications of this decision will be discussed in section 4.13.

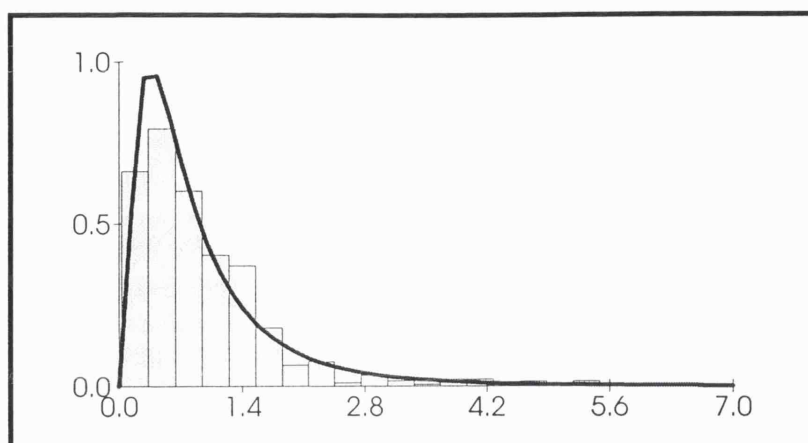


Figure 4.17 Dispensing times in hours (grey bars; $n = 604$ ward pharmacy order forms) compared to the lognormal $(0.97, 0.95)$ distribution (black line).

4.11 Times and durations of porters' ward deliveries

4.11.1 Methodology

It was decided to ask the pharmacy porters to give the information required. Observation was considered too time consuming and potentially intrusive.

4.11.2 Definitions

The *times* of the porters deliveries were defined as the times at which the porters left the pharmacy department each day. The *duration* of the delivery was defined as the time interval between the porter leaving the pharmacy department and his arriving on the study ward.

4.11.3 Data collection methods

The porters responsible for delivering dispensed medication to each study ward were asked to give the times at which they left the pharmacy department and to estimate the time taken to reach the study ward concerned.

4.11.4 Results

The times at which porters left the pharmacy department were reported to be noon, 2 pm, 3.30 pm and 5.30 pm on weekdays. On Saturdays, there is a porters' visit at 12.30 pm; there are no porters' deliveries on Sundays. The time taken to reach each study ward was estimated to be 30 minutes. Since the time of the porters' last daily delivery meant that dispensed items would arrive on the ward during the 6 pm drug round, ward staff were asked whether dispensed medication arriving during that round would be administered; they said it would be administered during the 6 pm round about 50% of the time. Delivery of medication to the ward was therefore represented accordingly in the model.

4.12 Frequency with which drugs are obtained from pharmacy between ward pharmacists' visits

If unavailable drugs are required urgently, nursing staff sometimes take patients' drug charts to the pharmacy department for dispensing instead of waiting for the next ward pharmacists' visit. In particular, nurses often take drug charts to the pharmacy department on Sundays when there are no ward pharmacy visits. If the pharmacy department is closed, nursing staff may also contact the resident pharmacist and request that the medication is dispensed. However, the proportion of newly prescribed medication orders that are dispensed following nurses' visits to the pharmacy department or calls to the resident pharmacist was unknown.

4.12.1 Methodology

It was decided to collect these data during the fourteen-day study of prescribing described in section 4.5. This would allow the numbers of medication orders dispensed following nurses' visits to the pharmacy department or calls to the resident pharmacist to be compared with the numbers of unsupplied medication orders for non-stock drugs at each point in time.

Following discussions with pharmacy staff, it was concluded that it was impractical for dispensary staff to record details of all drug charts brought to the pharmacy department by ward staff. Because the researcher was familiar with the signatures of all pharmacists in the hospital, it was decided instead to use the signatures on the study ward drug charts to ascertain whether non-stock items had been supplied by the ward pharmacist or by another pharmacist. Resident pharmacists record details of all calls, and their records could therefore be used to identify any items dispensed for either ward during the study period.

4.12.2 Data collection methods

The signatures in the pharmacy section of each drug chart were examined for all non-stock medication orders prescribed during the fourteen-day study. Any signatures that belonged to pharmacists other than the regular ward pharmacist were identified. Resident pharmacists' records for the study period were also examined. Dispensing reports for each study ward were then produced using the pharmacy computer system, to confirm that every dispensed item had been accounted for.

4.12.3 Results

During the study period, the regular ward pharmacists visited the study wards each weekday. Any signatures on drug charts that were not the ward pharmacists' therefore represented items dispensed between their visits.

Surgical ward

No items were dispensed by the resident pharmacist, and none were dispensed following nurses taking charts to the pharmacy at any time during the study period, including Sunday mornings. However, there were no unsupplied items on either Sunday morning that could have been supplied.

Medical ward

No items were dispensed by the resident pharmacist and during the Mondays to Saturdays

of the study period, no items were dispensed following nurses taking charts to the pharmacy. However, two newly-written medication orders were dispensed on the first Sunday and three on the second. There was one additional medication order written on the first Sunday morning, but this was not supplied until after the ward pharmacist's Monday morning visit.

In view of these findings, it was assumed that the resident pharmacist would not be called and that nurses would not take drug charts to the pharmacy department between Mondays and Saturdays. Similarly, any medication orders written on Sunday afternoons would not be dispensed until after the ward pharmacist's Monday morning visit. However, it was assumed that if any new medication orders were written between the Saturday pharmacist's visit and mid morning on Sunday, the relevant drug charts would be taken to the pharmacy department on the Sunday morning and the medication dispensed.

4.13 Discussion

Data were collected and parameters selected to represent each model input variable. As well as providing values for use in the model, this data collection led to a deeper understanding of the drug distribution system. For example, the results suggest that about 60% of all medication orders are written on admission and that the majority of these are for drugs that patients were taking prior to their admission. Such findings have useful implications for designing strategies to improve the efficiency of the drug distribution system.

In some cases, however, data were partially incomplete, samples relatively small or simplifying assumptions made. For example, parameters describing the times and frequencies of medication order writing and the characteristics of the drugs prescribed were determined from only fourteen days' data. It is not known how much variability exists amongst different weeks in terms of prescribing patterns, and the labour-intensive nature of data collection precluded the collection of additional data. However, a pharmacy workload report suggested that the numbers of items dispensed for the study wards during each study week were not atypical. The numbers of admissions during each

study week were also in the range expected. A further limitation of the method used to determine times of medication order writing is that the wards were visited by the researcher only every two hours between 8 am and 8 pm. Some details of peak and trough prescribing rates may therefore have been lost. However, more frequent visits would have been impossible without an additional data collector, as it sometimes took more than an hour to locate all the drug charts and record the relevant information for the two study wards.

Admission times were also determined using data collected during the fourteen-day study, although a much larger sample of data was used to study days of admission. Admission times were recorded for only 95% of patients admitted to the surgical ward and only 93% of patients admitted to the medical ward during the study period; it was assumed that the patients for whom admission times were unknown were admitted at similar times to those for whom admission times were known. It was also assumed that equal numbers of patients were admitted to the medical ward each weekday.

Exponential distributions were used to represent ward lengths of stay, in spite of the goodness-of-fit being poor. The poor goodness-of-fit may be partly due to the sample of real world length of stay data being very large (Law and Kelton, 1991: 382). Another potential contributing factor is that the real world data may have been truncated. Patients with very long ward lengths of stay would be less likely to have been discharged during the time for which data were available and their lengths of stay therefore not recorded. Finally, the patient populations involved may be heterogeneous, with different subgroups having different length of stay distributions. For example, Millard and McClean (1994) suggest that for many patient groups, length of stay is best represented using the sum of two or even three different exponential distributions. However in the present study, single exponential distributions gave simulated admission rates and bed occupancies that corresponded to those observed in the real world; these were therefore considered satisfactory.

The times and durations of the pharmacists' visits were determined from only fourteen days' data. However, the weeks chosen for the study were considered representative as

only the regular ward pharmacists visited each study ward and neither visited other wards during this time.

Another case in which simplifying assumptions were made was for the delays incurred during the dispensing of non-stock medication. One distribution of dispensing times was selected for use in the model, in spite of there being significant differences in dispensing times for ward pharmacy order forms brought to the pharmacy department at different times of day and for ward pharmacy forms with different numbers of items.

Although all of these assumptions were considered to be justified, it was important to determine the extent to which they affected the model's results. Sensitivity analysis, in which changes are made to a model's input parameters and the effects on its output explored, is recommended in such cases (Law and Kelton, 1991). The sensitivity analyses carried out in the present study will be considered in Chapter Six. First, however, the next chapter will describe the construction of the final version of the simulation model, its verification and its validation.

Chapter Five: Model construction

This chapter describes how the final version of the simulation model was constructed, verified and validated. First, a brief account will be given of the model's structure, before describing some of the problems encountered during its construction and how they were resolved. Model verification and validation will then be considered.

5.1 Objectives

1. To describe the construction of the final version of the simulation model.
2. To describe some of the key problems encountered during model construction.
3. To address model verification and validation.

5.2 Description of the model

In this section, a brief description of the simulation model will be given; Appendix 6 gives a more detailed description of the model's construction and shows its on-screen appearance. A full-size diagram of the whole model is also included inside the back cover of this thesis.

The model was constructed using hours as the time unit throughout; time zero was taken to be midnight between Sunday night and Monday morning. Many assumptions, both implicit and explicit, were made during model construction. Many relate to the data used as model inputs and were discussed in Chapter Four. Others relate to the model's structure and logic, and will be briefly discussed in this section. A full account of all assumptions made is given in Appendix 7.

The model can be considered to consist of nine sectors, each of which performs a distinct function. Figure 5.1 summarises the relationships amongst these sectors, each of which

will be individually described.

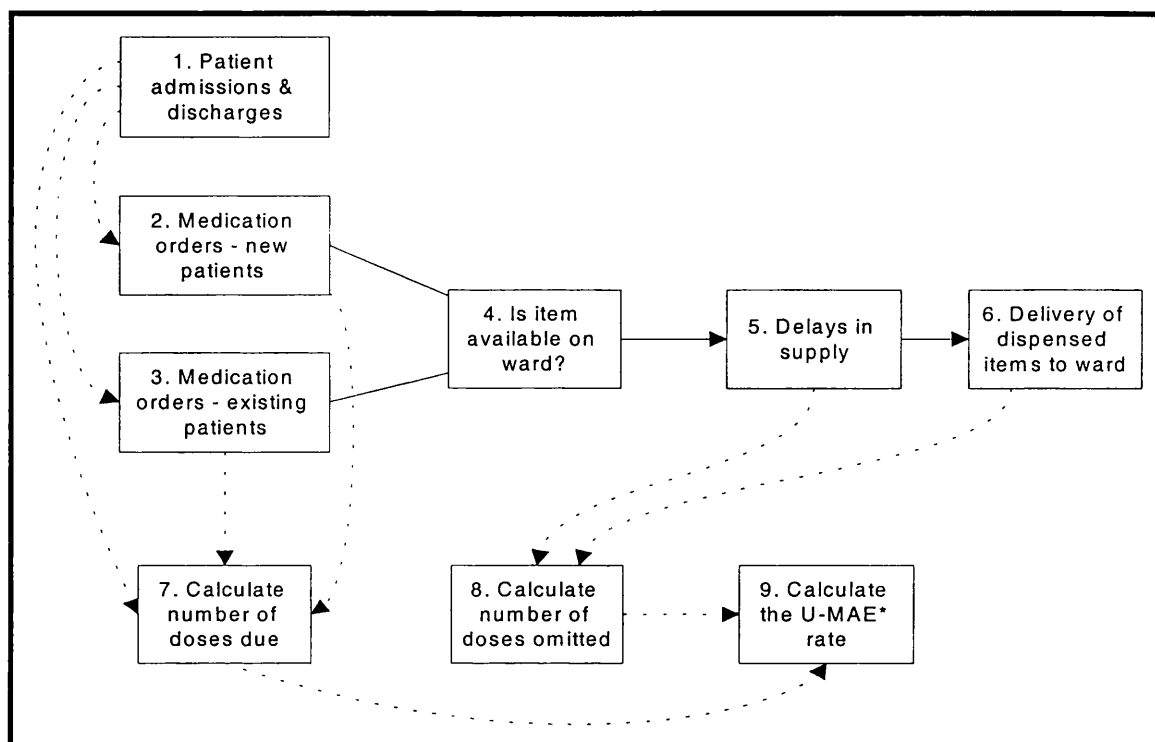


Figure 5.1 Overview of the model, showing the relationships amongst the nine sectors. Unbroken lines represent the flow of simulated medication orders; broken lines represent the flow of information within the model.

* U-MAE: unavailability-related medication administration error

5.2.1 Sector 1 - Patient admissions and discharges

This sector of the model represents ward admissions and discharges. Its structure is summarised in figure 5.2. Potential admissions were considered to occur according to a non-stationary Poisson process. This means that the inter-arrival times were represented by an exponential distribution, the mean of which varies with time. The reciprocal of the mean patient arrival rate for each hour of the day (section 4.7) was used as the mean of the exponential distribution (Taha, 1995). The use of a non-stationary Poisson process to represent arrival patterns is based on assumptions that arrivals can occur only one at a time and that the number of arrivals within a given time interval is independent of the number in previous time intervals (Law and Kelton, 1991). Both of these assumptions were considered reasonable in the present study.

If the simulated ward is already full, potential admissions immediately exit the model. Otherwise, the simulated patients enter the ward, where each remains for a time period randomly selected from the appropriate length of stay distribution (section 4.8). Simulated patients exit the model once their length of stay has been exceeded. Only admissions to each study ward were considered; admissions to other wards in the hospital were outside the scope of the model. The implications of representing patient admissions in this way will be discussed in more detail in section 5.3.2.

Whenever a simulated patient is admitted, information is transferred to sector 2 of the model to indicate that an admission has occurred. Whenever a patient is discharged, this information is sent to sector 7 so that the removal of that patient's drug chart from the ward can be simulated. The number of patients on the ward at any one time is output to sector 3, which simulates medication order writing for existing patients.

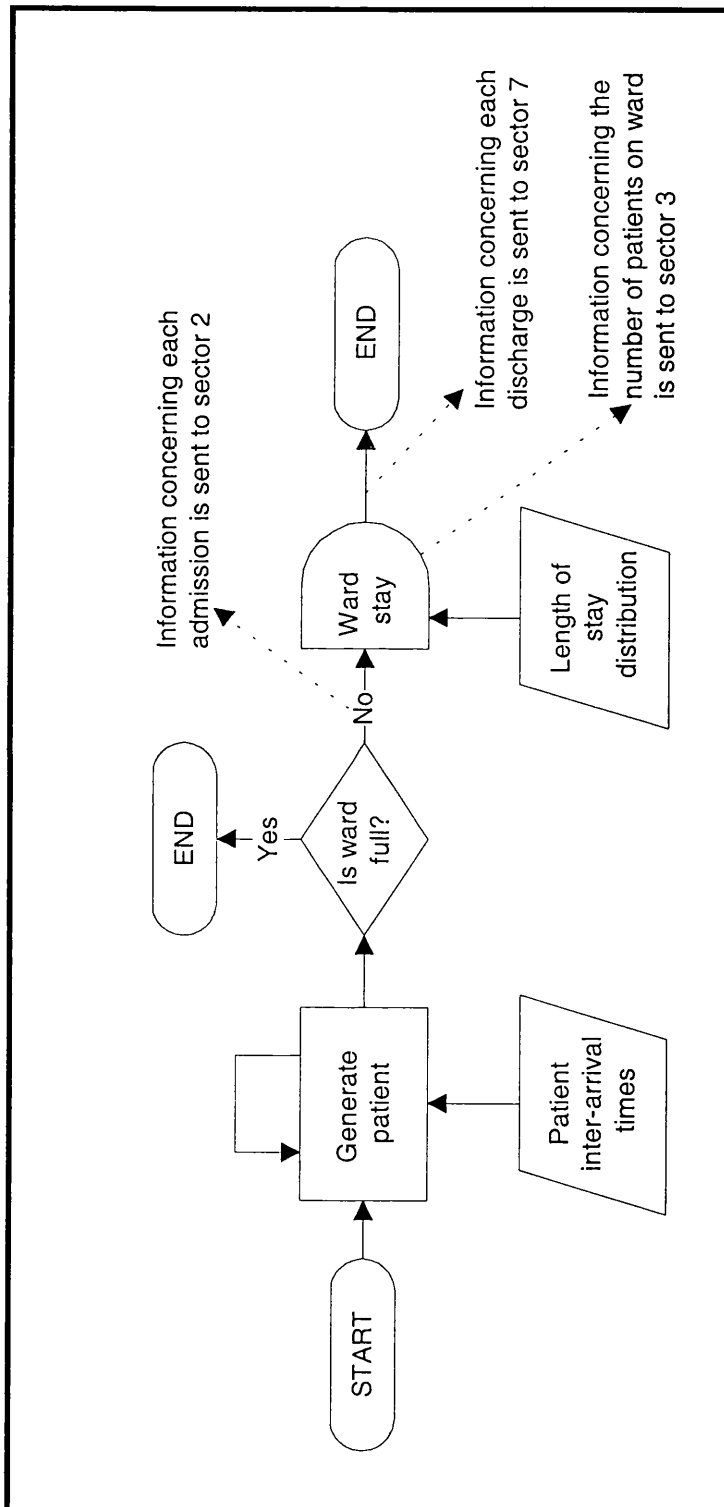


Figure 5.2 Sector 1 - Patient admissions and discharges.

5.2.2 Sector 2 - Medication order writing for newly admitted patients

This part of the model (figure 5.3) represents the writing of a new drug chart for each patient admitted. The number of medication orders generated for each simulated admission varies according to the probability distributions described in section 4.5.5.2. The characteristics of each simulated medication order are described using a number of attributes. These indicate whether or not the order is for a drug that the patient was taking prior to their admission (attribute name: PRIOR), whether or not the drug is ward stock (STOCK) and the dose regime (REG). For each medication order, the value of each attribute is determined according to the probability distributions described in section 4.6. Information corresponding to each new medication order is sent to sector 7 of the model, where the number of doses due is calculated.

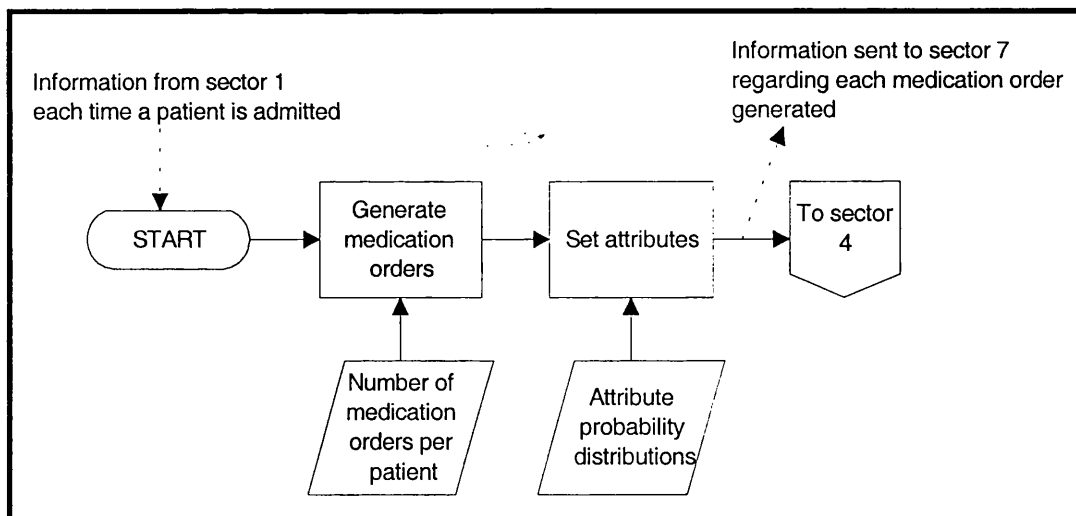


Figure 5.3 Sector 2 - Medication order writing for newly admitted patients.

It was assumed on an *a priori* basis that there was no relationship between the time at which a patient was admitted and the number of medication orders written, the probability of each medication order being for a drug that the patient was taking prior to admission, the probability of each drug being ward stock or the dose regimes of each drug prescribed.

5.2.3 Sector 3 - Medication order writing for existing patients

This sector (figure 5.4) represents medication order writing for patients already present on the ward. Simulated medication orders are generated according to a non-stationary Poisson process with a frequency that varies according to the number of patients on the ward, the time of day and the day of the week. Times between successive medication orders were therefore represented using an exponential distribution, the mean of which varies with time. The reciprocal of the mean number of medication orders written per patient per hour (section 4.5.5.3) was used as the mean of the exponential distribution (Taha, 1995). Information giving the number of patients on the simulated ward is obtained from sector 1. As in sector 2, the characteristics of each medication orders are described using the attributes PRIOR, STOCK and REG. Information corresponding to each new medication order is sent to sector 7 of the model.

Again, it was assumed that there was no relationship between the time of medication order writing and the number of medication orders written, the probability of a medication order being for a drug taken prior to admission, the probability of the drug being ward stock or the dose regime of the drug prescribed.

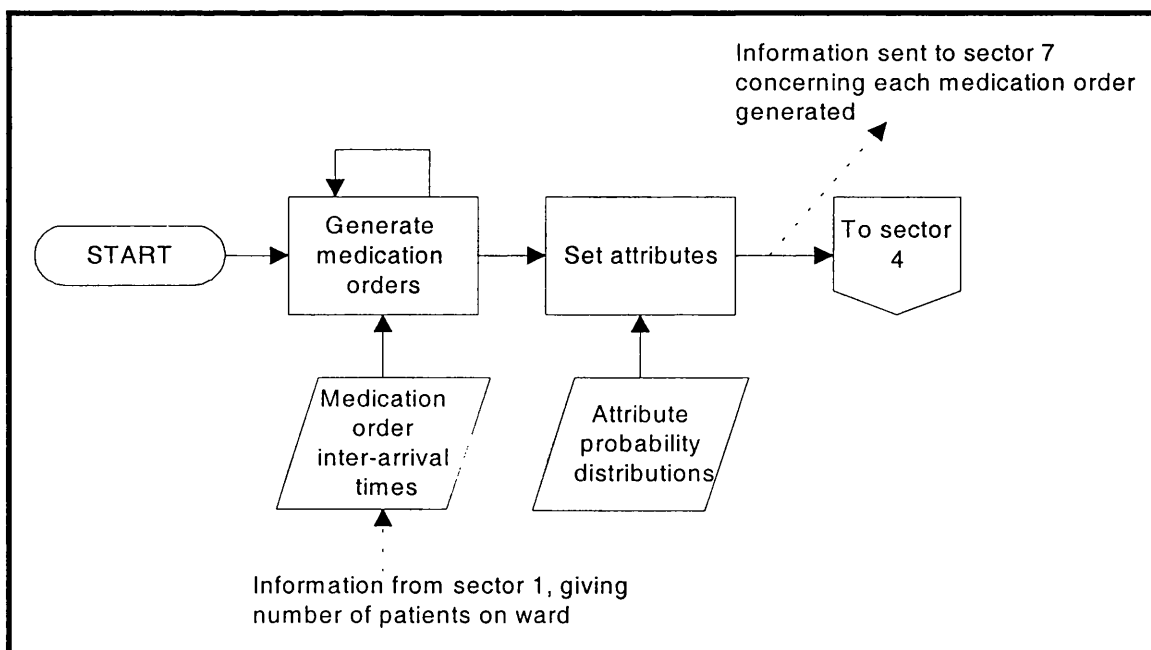


Figure 5.4 Sector 3 - Medication order writing for existing patients.

5.2.4 Sector 4 - Determine whether item is available on ward

This sector (figure 5.5) determines whether or not simulated medication orders are for drugs that are available on the ward. If the attribute STOCK indicates that a medication order is for a stock drug, it does not have to be dispensed and therefore leaves this part of the model. However, if the simulated medication order is for a non-stock drug, it continues to sector 5.

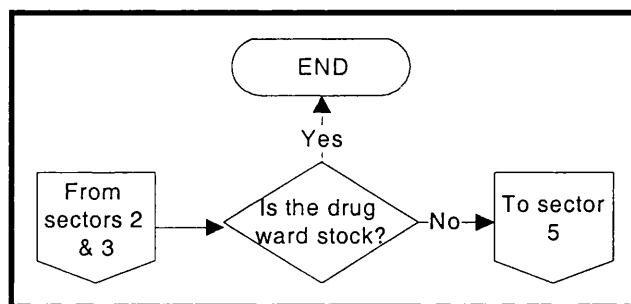


Figure 5.5 Sector 4 - Determine whether item is available on ward.

It was assumed that stock medication would always be available on the ward for administration, and that in accordance with hospital policy, doses of newly prescribed non-stock drugs would not be obtained from other patients or from other hospital wards.

5.2.5 Sector 5 - Delays in supply

This sector (figure 5.6) represents the delays incurred during the dispensing and supply of non-stock medication. Whenever a simulated medication order enters this sector, information corresponding to that order is sent to sector 8 of the model, so that the number of doses omitted during the dispensing and supply processes can be calculated. Simulated medication orders are considered to wait on the ward until the ward pharmacist's next scheduled visit. The time and duration of each ward visit are determined using the distributions described in section 4.9; the delays incurred during the dispensing process are determined according to the distribution described in section 4.10.

A number of key assumptions were made during the construction of this sector. First, it was assumed that the ward pharmacist would transcribe details of every unavailable medication order immediately after his or her arrival on the ward. Any medication orders written during the remainder of the ward pharmacist's visit would therefore not be transcribed until the next visit. This assumption was considered appropriate as medical staff do not generally draw pharmacists' or nurses' attention to newly written medication orders.

Second, it was assumed that the times and durations of the Saturday morning ward pharmacists' visits were similar to those of the weekday visits. Pharmacists do not inspect each patient's drug chart on Saturdays and the time spent on each ward is therefore much less than during the week. However, weekend staffing arrangements mean that there is usually only one pharmacist per hospital wing; the time taken to visit every ward in a hospital wing was considered to be similar to the time taken to inspect all the drug charts on one ward during a weekday morning visit.

Third, it was assumed that the time at which nurses bring drug charts to the pharmacy department on a Sunday is similar to the time at which ward pharmacists deliver ward pharmacy order sheets to the pharmacy during the week.

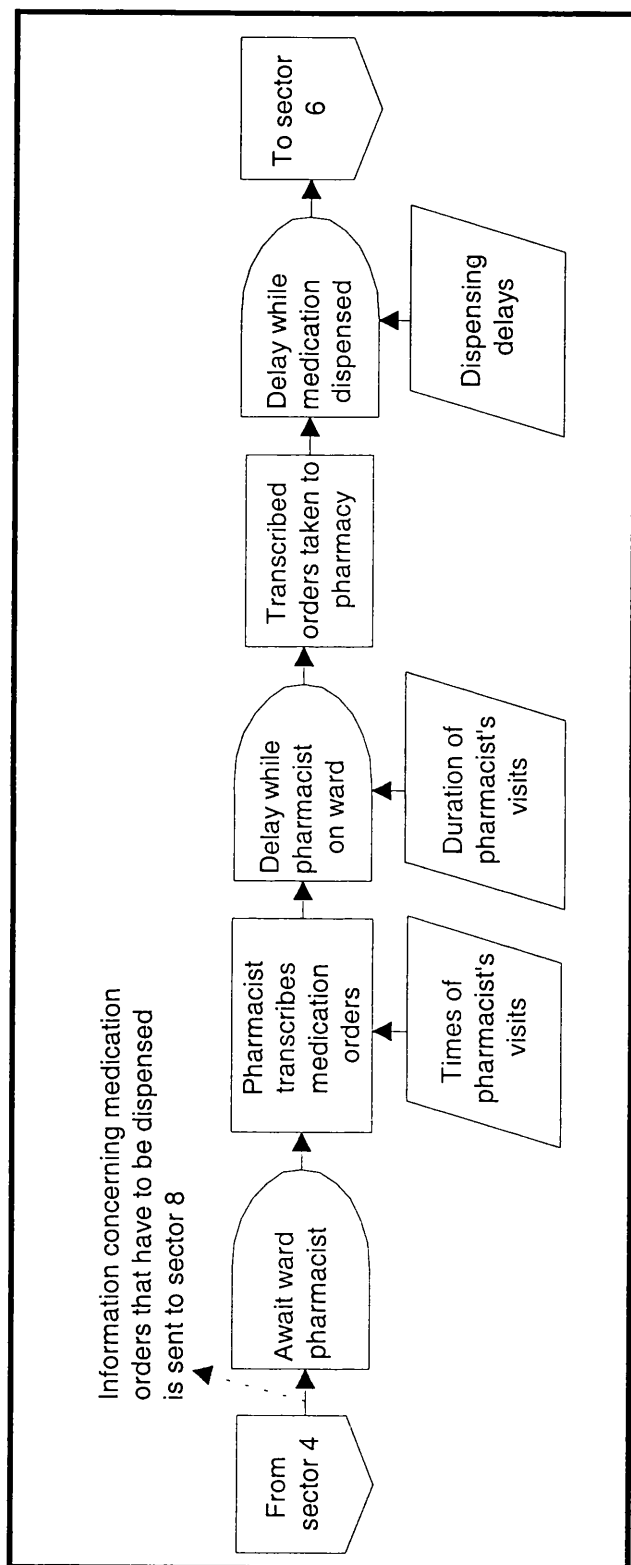


Figure 5.6 Sector 5 - Delays in supply.

A fourth assumption was that weekend dispensing times were similar to weekday dispensing times.

Fifth, it was assumed that all medication orders are dispensed and delivered to the ward before the pharmacy department closes at the end of each day. This reflects standard practice in the study hospital

Sixth, it was assumed that the details of every drug required for the same ward would be recorded on one ward pharmacy order form and that the items on each form would be dispensed together. Again, this reflects standard practice in the study hospital.

Dispensing and checking procedures were represented as one process rather than individually.

A final assumption made was that all drugs required would be in stock in the pharmacy department.

5.2.6 Sector 6 - Return of dispensed medication to the ward

This sector (figure 5.7) represents the delivery of dispensed medication to the ward. Simulated porters' deliveries are scheduled for specific times corresponding to those in the real world (section 4.11). In the model, additional 'deliveries' are also scheduled for the time at which the pharmacy department closes on each day, representing nurses who are asked to collect any dispensed medication that remains in the department at closing time. Whenever a dispensed item is delivered to the ward, corresponding information is sent to sector 8 of the model to indicate that the medication concerned has been supplied.

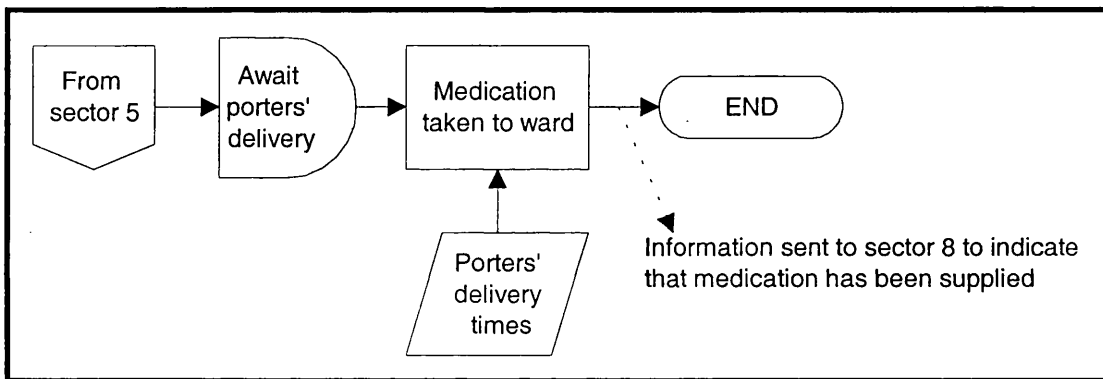


Figure 5.7 Sector 6 - Return of dispensed medication to the ward.

It was assumed that as soon as the porters' box containing dispensed medication arrives on the ward, the medication is available for administration. The time taken to unpack the box was therefore considered to be negligible.

5.2.7 Sector 7 - Calculate number of doses due

This sector (figure 5.8) calculates the number of doses scheduled to be administered. Information regarding each simulated medication order is input from sectors 2 and 3. Simulation items representing current medication orders cycle through model blocks representing each of the four daily drug rounds (6 am, noon, 6 pm and 10 pm). At each simulated drug round, the number of doses due during that round is determined and added to a cumulative number of doses due. This information is transferred to sector 9 of the model. It was assumed that all doses prescribed are to be administered; the effects of patients being 'nil-by-mouth' and other contraindications to medication administration were considered to be negligible.

Whenever a patient is discharged from the simulated ward in sector 1, an appropriate number of medication orders are removed from those cycling through the drug rounds, to represent the removal of that patient's drug chart from the ward. Between each pair of drug rounds, a small number of simulated medication orders are also removed, representing medication orders that are discontinued during a patient's hospital stay, for example because the drugs concerned are no longer needed (section 4.5.5.4). The discontinuation of active medication orders will be discussed in more detail in section 5.3.4.

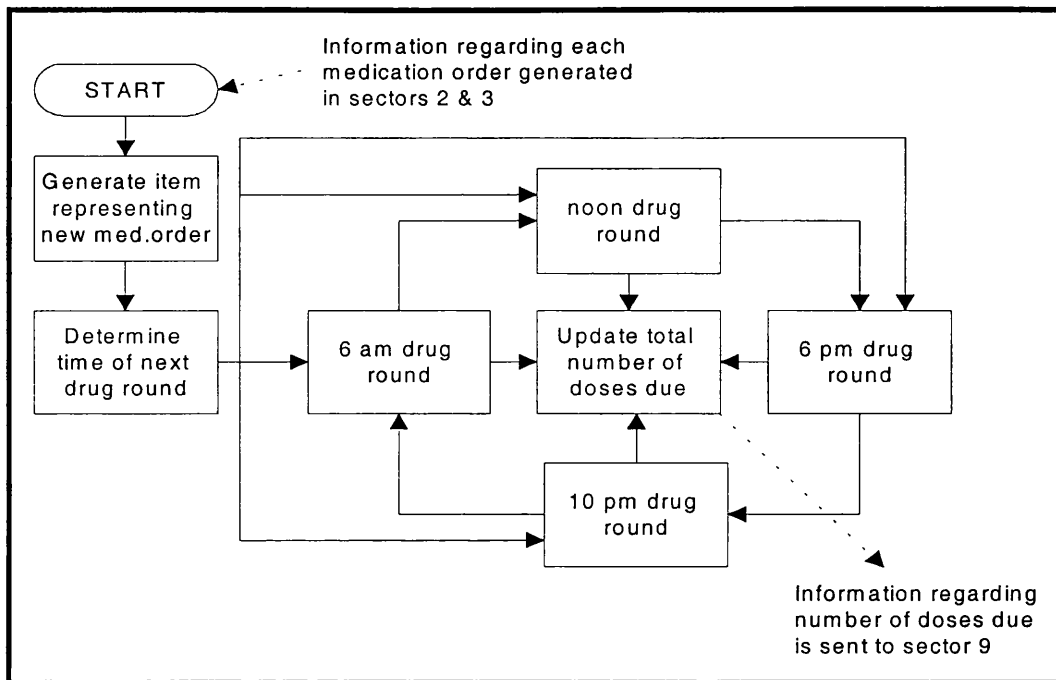


Figure 5.8 Sector 7 - Calculate number of doses due.

Not shown in the diagram are the discontinuation of simulated medication orders during patients' hospital stays and at discharge.

5.2.8 Sector 8 - Calculate number of doses omitted

This sector calculates the number of omissions that occur while unavailable non-stock orders are being supplied. Whenever a medication order is prescribed for a non-stock drug, a simulation item is generated in this sector. These simulation items cycle through model blocks representing the four daily drug rounds, in a similar manner to that described for sector 7. The cumulative number of doses omitted is calculated; this information is transferred to sector 9 of the model. As soon as simulated medication orders are delivered to the ward in sector 6, the relevant simulation items are removed from sector 8 because they are no longer unavailable.

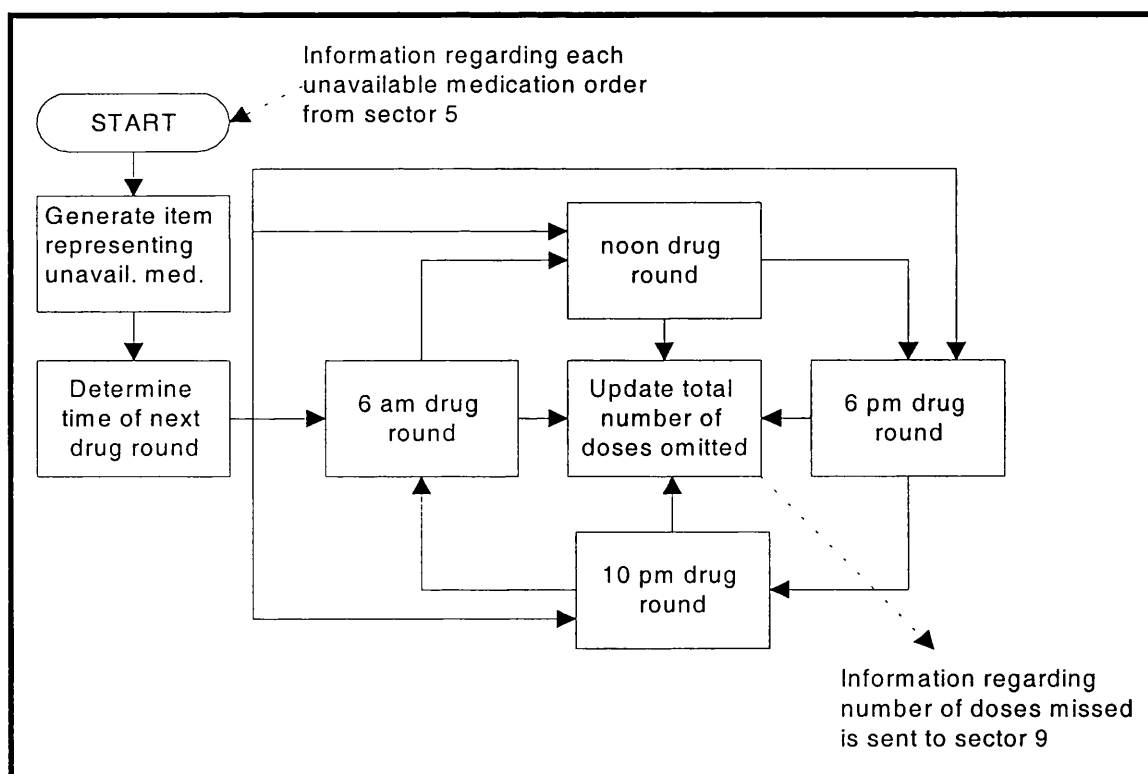


Figure 5.9 Sector 8 - Calculate number of doses omitted.

Not shown is the removal of simulation items from this sector once the corresponding medication orders have been supplied.

It was assumed that if doses are unavailable at the time of the drug round, the doses concerned are not given at a later time. In practice, doses omitted due to unavailability

are sometimes given during a later round if the drug subsequently becomes available. However the effect of this practice was considered to be negligible. Drug rounds were also considered to occur at the exact times specified (6 am, noon, 6 pm and 10 pm). In practice, each drug round can take up to two hours to complete. However, to avoid unnecessary model complexity, drug rounds were represented as occurring instantaneously at the times specified.

It was assumed that medication orders are never discontinued and patients are never discharged before any outstanding medication orders have been supplied. It was also assumed that all previously dispensed medication is available for administration.

5.2.9 Sector 9 - Calculate the U-MAE rate

In this sector (figure 5.10), the cumulative number of doses omitted and the cumulative number of doses due are used to calculate the percentage U-MAE rate.

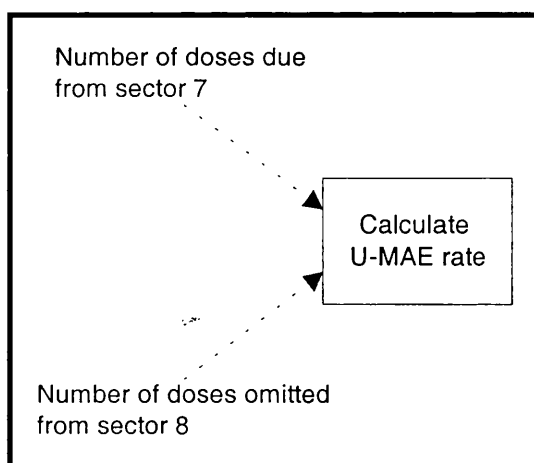


Figure 5.10 Sector 9 - Calculate the U-MAE rate.

5.3 Problems encountered during model construction

In this section, some specific problems encountered during model construction will be discussed, together with the solutions adopted. These problems included how to generate simulation items according to a frequency that varies with time, how to generate appropriate numbers of simulated ward admissions, how to model times of patient discharge and how to represent the removal of active medication orders from the ward.

5.3.1 Generation of simulation items according to a frequency that varies with time

Using Extend, the generation of simulation items is usually carried out using a generator block specifically designed for this purpose. The generator block creates simulation items with inter-arrival times distributed according to a specified distribution. For example, the block can be set up so that inter-arrival times are exponentially distributed about a specified mean. If the model constructor wishes the mean of the distribution to vary with time, the generator block can be connected to an 'input data' block, from which different values are output depending on the simulation time (figure 5.11). This can be used to produce simulation items with inter-arrival times that vary according to an exponential distribution, where the mean of the distribution varies with time.

In the present study, the frequencies of patient admissions and medication order writing were both considered to vary according to time; this approach was therefore required. However, problems were encountered during model construction, which was initially carried out using Extend version 3.2. It was noted that if the mean inter-arrival time changed dramatically with time, the numbers of simulation items generated were considerably lower than anticipated. The cause of this phenomenon was found to be the way in which the generator block determined the time at which the next simulation item was due. For example, the mean inter-arrival time between successive medication orders could be 10 hours between midnight and 8 am, 1 hour between 8 am and noon and 2 hours between noon and 6 pm. If a medication order was generated just prior to 8 am, the next scheduled medication order would be likely to be scheduled for after noon. The

peak prescribing period between 8 am and noon would therefore be ignored.

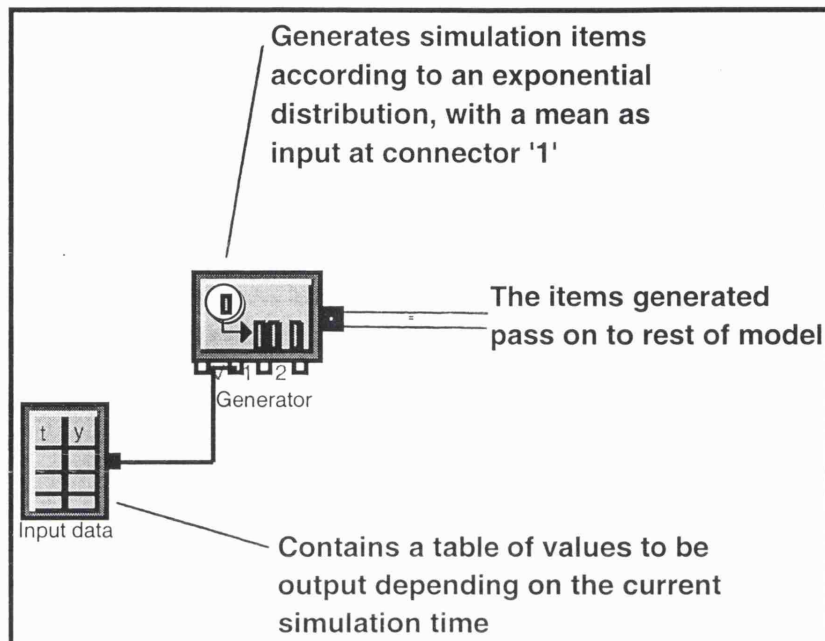


Figure 5.11 Generation of simulation items according to a frequency that varies with time.

Examination of other simulation packages revealed that some had an option that allowed new input values to interrupt current inter-arrival rates in generator-type blocks. The generator block included in Extend version 3.2 had no such option. This problem was discussed with staff at Extend's technical support centre, who then reprogrammed the generator block so that new inputs could interrupt the current inter-arrival rate. The modified generator block was subsequently used throughout the model's construction so that new inter-arrival rates were always taken into account and simulation items generated at the frequencies desired. The modified generator block has now been incorporated into Extend version 4.0.

5.3.2 Generation of appropriate numbers of ward admissions

Another problem identified was that the percentage bed occupancy on each simulated ward was consistently lower than that expected. This was because the model was

constructed so that if the ward was full, simulated patients could not be admitted and exited the model. This resulted in about 15% of all simulated patients exiting the model instead of entering the ward. In the real world too, patients sometimes have to be admitted elsewhere if there are no beds vacant on the ward in question. However, the data used to generate the simulated patients in the model were based on those patients who were actually admitted to the real world ward (section 4.7); they did not include patients who were potential admissions but had to be admitted to another ward or hospital because the study ward was full. In order to overcome this problem, the mean admission rates used in the model were increased by 15%. Following this intervention, satisfactory admission rates and bed occupancies were produced for each simulated ward.

5.3.3 Times of discharge

It had been intended to ensure that simulated patients were discharged at times similar to those observed in the real world. However, the way in which ward length of stay was represented in the model made this impossible to achieve. In the model, ward length of stay was represented using a continuous distribution of hours since admission (section 4.8). Simulated patients were therefore discharged at whatever time of day their allocated length of stay happened to end. In contrast, in the real world, discharges are most likely to occur between 8 am and 6 pm (section 4.7.5.3). However, changing the simulated discharge times to reflect the times at which discharges occur in the real world would have required changing either the admission times or the lengths of stay. It was concluded that it was more important that these reflected the real world situation, and it was therefore decided to allow simulated discharges to occur at whatever time the ward lengths of stay ended. This simplification was considered unlikely to affect the results of the simulation as the time at which a simulated patient is discharged affects only the time at which medication orders are removed from the pool of current medication orders. The number of current medication orders is used in the model to calculate the number of doses due and the precise times at which medication orders are removed are unlikely to significantly affect the results obtained.

5.3.4 Discontinuation of active medication orders

Active medication orders were considered to be discontinued whenever a patient was discharged, and at intervals throughout a patient's hospital stay. The frequencies at which medication orders were discontinued during a patient's stay were initially represented using the figures given in section 4.5.5.4. Data concerning the number of active medication orders on each discharged patient's drug chart were also collected during the fourteen-day observational study described in section 4.5. These data were used during the initial stages of model construction to produce a distribution describing the number of simulated medication orders that should be removed following each patient discharge. However, the use of these data in the model resulted in the number of active medication orders continuously increasing on the surgical ward and continuously decreasing on the medical ward. Inspection of the figures used revealed that during the fourteen-day observational study, the numbers of medication orders written and the numbers of medication orders discontinued were not equivalent on either ward.

This problem was solved using a combination of two approaches. The first involved calculation of the number of medication orders that would have to be discontinued during patients' hospital stays to keep the number of active medication orders in equilibrium. These figures, which were used in the final version of the model, were 0.09 medication orders per patient per day on the surgical ward and 0.1 on the medical ward. Second, the removal of active medication orders at patient discharge was represented using a Poisson distribution with a mean equivalent to the current mean number of active medication orders per patient. Using this approach, the numbers of medication orders removed per discharged patient were similar to those observed in the real world, while ensuring that the number of active medication orders remained relatively constant throughout the simulation.

5.4 Verification and validation

A key issue in any modelling study is whether or not a model is an adequate representation of reality. The extent to which a model reflects the system of interest is usually referred to as the model's validity. However, considerable confusion exists within the literature regarding this terminology; other terms encountered include acceptability, accuracy, analysis, assessment, calibration, certification, confidence, credibility, evaluation, performance, qualification, quality assurance, reliability, testing, validation and verification (Balci and Sargent, 1984). To further confuse matters, the same words are sometimes given different meanings by different authors (Naylor and Finger, 1967; Sargent, 1982). In keeping with more recent texts (Law and Kelton, 1991; Banks *et al*, 1996; Pidd, 1998), the term *validation* will be used in the present study, meaning 'ensuring that a model is an adequate representation of the system of interest for the intended purpose'. *Verification* will be used to refer to the separate but important concept of ensuring that a simulation model performs as intended and is free from programming errors.

Verification and validation therefore have different objectives. The relationships between the two concepts have been considered by several authors. For example, Sargent (1982) proposes a framework that consists of the real world problem entity, a conceptual model (a logical or verbal representation of the problem entity) and a computer model (the conceptual model represented on a computer). Validation is considered to consist of conceptual model validity (the extent to which the theories and assumptions underlying the conceptual model are correct), operational validity (the extent to which the characteristics of the problem entity are represented in the simulation model) and data validity (the extent to which the data used during model construction are adequate and correct). Verification is considered to mean ensuring that the computer programming and implementation of the conceptual model are correct. Pidd (1998), however, contends that with the advent of visual interactive modelling software (such as Extend, Ithink and Simul8), there is less difference between a conceptual model and its computer implementation. A simulation model may be created directly on the computer screen

without first developing a separate conceptual model. Pidd suggests that in these cases the difference between verification and validation is artificial and can be abandoned.

In the present study, although the model was constructed on-screen, it was decided to consider verification and validation separately. It was considered that errors in model construction were likely due to the model's relatively large size and complexity and that a verification stage, distinct from validation, was essential. Verification and validation will therefore each be discussed in turn.

5.4.1 Verification

Naylor and Finger (1967) considered verification to be another word for validation. It was Fishman and Kiviat (1968) who first introduced verification as a separate concept, that of ensuring that a simulation model behaves as intended. Others refer to this process as 'debugging' (Law and Kelton, 1991). Many different methods have been suggested for model verification (van Horn, 1971; Sargent, 1982; Law and Kelton, 1991), these include the following:

1. Use simulation software rather than a general purpose programming language to reduce the likelihood of programming errors.
2. Write and verify the model in stages.
3. Perform a structured walk-through of the computer program.
4. Ask someone who did not build the model to check its construction.
5. Produce a report of the activity in key parts of the model during a simulation run.
6. Examine an animated simulation run.
7. Compare the simulation output with results obtained from analytical models.
8. Run the model under simplifying assumptions for which the expected output is known or can be calculated by hand.
9. Check the mean and variance of generated distributions.
10. Run the model using extreme values for key inputs and examine the output for reasonableness.

5.4.1.1 Verification methods used in the present study

In the present study, many of the above approaches were used. The model was written in stages using simulation software and verified on a sector-by-sector basis. It was ascertained that each part of each sector was performing as intended; animation and simulation reports were used to aid this process where necessary. Wherever possible, sections of the model were run under simplifying assumptions, so that the output expected could be calculated by hand. Distributions of values generated by the model were also compared to those expected. Another person familiar with the use of Extend examined the model's construction and performed a structured walk-through together with the researcher.

During the verification process, several problems were identified and the causative errors in model construction resolved; a full report of the model's verification is given in Appendix 8. Once verification had been completed, the researcher was confident that the simulation model was performing as intended.

5.4.2 Validation

One of the first and most influential papers relating to validation was Naylor and Fingers' 'Verification of computer simulation models' (1967). These authors used the word 'verification' interchangeably with 'validation', meaning the extent to which a model represents the system of interest. In this paper, parallels are drawn between simulation models and the laws of science. For example, according to Popper's theory of falsificationism, it is impossible to state that a scientific law is valid and instead we should speak of gradually increasing confidence in its validity. If a series of tests of a scientific law do not produce anything to refute its validity, then confidence in the law grows with each step. Naylor and Finger suggest that the same is true for simulation models. The authors then describe the three major methodological positions of rationalism, empiricism and positive economics in relation to the validation of simulation models. Rationalism maintains that assumptions are so obvious that people should be able to state whether or not they are true and there is therefore no need to test them

empirically. Empiricism, in contrast, is a positivist view and refuses to accept any assumptions that cannot be independently verified. Positive economics takes a third view, that the validity of a model rests not on the validity or otherwise of its assumptions and structure, but on its ability to predict the behaviour of the variables of concern.

Naylor and Finger suggest that simulation models should be validated using a multi-stage approach that takes each of these methodological positions into account:

‘Multi-stage verification [validation] implies that each of the aforementioned methodological positions is a necessary procedure for validating simulation experiments, but that neither of them is a sufficient procedure for solving the problem of verification [validation]’

(Naylor and Finger, 1967: B-95).

The first step of the multi-stage process described is to construct a set of assumptions describing the behaviour of the system of interest; any assumptions that cannot be accepted on *a priori* grounds should be rejected. The second step is to test assumptions empirically. The final test should be of the model’s ability to predict the behaviour of the system of interest. Naylor and Finger suggest that this multi-stage approach is the most cost-effective, since it is cheaper to reject an assumption on *a priori* grounds than to test it statistically; similarly it is cheaper to test assumptions statistically than to compare a model’s output with the real world system. However, no recommendations are made regarding the situation in which the real system does not exist.

Naylor and Fingers’ recommendations have been further refined by many authors, and are generally considered to mean ensuring high face validity by involving users of the model in its construction, statistically validating model assumptions and comparing the model’s input-output transformations to those of the real system wherever possible (van Horn, 1971; Law and Kelton, 1991; Oakshott, 1997). More recently, Kleindorfer *et al* (1998) have suggested that a fundamental problem with Naylor and Fingers’ approach is that rationalism and empiricism both imply that validity is absolute. However, Naylor and Finger themselves emphasise that this is not the case.

Other writers emphasise that validity depends on the purpose for which the model is

intended (Law and Kelton, 1991; Paul, 1998). A model that is considered valid for one purpose will not necessarily be valid for another. It is also considered essential that increasing and testing a model's validity is addressed throughout the modelling process and not as a separate stage at the end of the study (Hoover and Perry, 1989).

In the present study, it was decided to consider the three approaches to validity recommended by Naylor and Finger (1967). Specific methods suggested in the literature for increasing and testing a model's validity were therefore considered under the headings of face validity, testing assumptions and testing the representativeness of a simulation's output (van Horn, 1971; Sargent, 1982; Law and Kelton, 1991; Pidd, 1998).

5.4.2.1 Face validity

1. Involve people familiar with the system of interest in model construction.
2. Use data from the real world system as model inputs wherever possible.
3. Use existing or commonly accepted theory whenever possible. For example, a Poisson process can be used to represent arrival patterns if the arrivals occur one at a time and are independent of time or the number of previous arrivals (Law and Kelton, 1991).
4. Ask people knowledgeable about the system if the model and its assumptions are reasonable. Animation of the model may be helpful in order to demonstrate its behaviour.

5.4.2.2 Testing assumptions

1. Test assumptions using appropriate statistical tests.
2. Test the goodness-of-fit of any theoretical probability distributions used.
3. Use sensitivity analysis for any estimated parameters or distributions.

5.4.2.3 Testing the representativeness of simulation output data

1. Ask experts familiar with the system to try to differentiate between model output and real world data. This is often referred to as a Turing test (Law and Kelton, 1991).

2. Compare input-output transformations for the model and the real world system, using identical sets of historical input data if possible.
3. Test whether the model can predict how a new system will behave by implementing the new system.

Van Horn (1971) lists a number of validation methods in order of their value:cost ratio. He suggests that building models with high face validity, making use of existing knowledge and conducting simple empirical tests of the distributions used are the most cost-effective approaches. Sargent (1982) also alludes to the diminishing returns obtained with increasing validation efforts.

5.4.2.4 Validation methods used in the present study

A variety of approaches were adopted in the present study. Validity was considered at each stage of model construction; much of the following account therefore refers to those sections of the thesis in which specific aspects are addressed.

Face validity

During model construction, data from the real world were used wherever possible; data collection was discussed in detail in Chapter Four. Existing theory was also used where appropriate. For example, patient arrivals and the writing of medication orders for existing patients were both assumed to occur according to a non-stationary Poisson process. Face validity was assessed by the researcher, who had worked for five years as a hospital pharmacist, and by another pharmacist at the study hospital. All assumptions made were documented during model construction (Appendix 7) and carefully considered. It was confirmed that each was appropriate.

Testing assumptions

Assumptions were tested statistically wherever possible. For example, the assumption that weekly numbers of patient admissions were relatively constant was tested using historical data from the study hospital (section 4.7). Goodness-of-fit was assessed for all theoretical distributions used (section 4.4). It was also decided to use sensitivity analyses

whenever simplifying assumptions were made regarding input data. These sensitivity analyses will be described in Chapter Six.

Determining the representativeness of simulation output data

It was decided against performing a Turing test, as little is known about the behaviour of the true U-MAE rate and it was considered unlikely that the results of such a test would be meaningful. To investigate the representativeness of the simulation output, it was therefore decided to measure empirically the real world U-MAE rate for the two study wards, and compare these data to those predicted using the model. As a further exploration of the model's validity, it was also decided to implement a change to the drug distribution system and again compare the U-MAE rates observed with those predicted. These aspects of the present study will be considered in detail in Part D of this thesis.

Having constructed the model and considered its verification and validation, the next stage of the study was to perform experiments using the model, including sensitivity analyses where appropriate. The next chapter addresses these issues.

Chapter Six: Experimentation with the model

6.1 Introduction

This chapter explains how the simulation model described in Chapter Five was used to explore the effects on unavailability-related medication administration errors (U-MAEs) of different changes to the hospital drug distribution system. Experimental design and statistical analysis are as important for simulation modelling as for any other experimental technique; the chapter therefore begins with a discussion of simulation experimentation methods and gives the rationale for those adopted in the present study. An account will then be given of the alternative drug distribution systems tested using the model, before specifying the methods used to compare them and giving the results obtained. Sensitivity analyses will then be described. The chapter concludes with a discussion of the findings.

6.2 Objectives

1. To choose appropriate experimental methods for the simulation study.
2. To select a series of changes to the drug distribution system to test using the model.
3. To identify changes to the drug distribution system that are likely to significantly reduce U-MAEs.
4. To carry out a sensitivity analysis for the results obtained.

6.3 Simulation methodology

To explore the effects of changing the drug distribution system, it was necessary to simulate the existing traditional ward pharmacy system (the base case) on each ward plus a series of alternative systems. However, data obtained from any stochastic simulation represent only samples from a larger population; it is therefore essential that the samples

are representative and that appropriate statistical tests are used in their analysis (Fishman and Kiviat, 1968; Law and Kelton, 1991; Oakshott, 1997; Pidd, 1998). Before carrying out any simulation experiments, a number of issues had to be addressed. These included how to avoid initial bias in the simulation results, whether to use independent replications or batching, the length of each simulation run, the number of replications of each configuration, variance reduction and statistical analysis. Each of these will be considered in turn.

6.3.1 Avoiding initial bias

A simulation can be considered to be either terminating or non-terminating, depending on whether or not it has an obvious end (Law and Kelton, 1991). In terminating simulations, the system's transient behaviour is usually of interest, while in non-terminating simulations it is generally the system's long term behaviour that is of concern (Pidd, 1998). The present case is an example of a non-terminating simulation as it is the steady-state U-MAE rate that is of interest and thus there is no obvious point at which the simulation should end.

If a non-terminating simulation starts with all queues and processes empty, it can take some time before steady-state conditions are reached. Any data collected before steady-state conditions are achieved are unlikely to be representative of the system's long-term behaviour. Two methods have been recommended for avoiding such initial bias; these are the choice of appropriate initialisation conditions and the incorporation of a run-in time (Banks *et al*, 1996; Pidd, 1998). The first method, choice of appropriate initialisation conditions, involves setting the initial values in each part of the model to reflect typical steady-state values. Although simple in theory, this approach has been criticised as different initialisation conditions may be appropriate for different system designs, yet the use of different initialisation conditions for different configurations can itself bias the results obtained (Pidd, 1998). It can also be difficult to choose appropriate values. The second method involves determining the time required to achieve steady-state conditions, and delaying the collection of simulation results until after this time. A

suitable run-in time is usually determined by plotting the response variable against time, then either visually or statistically identifying the point at which steady-state conditions are reached (Law and Kelton, 1991; Banks *et al*, 1996). The disadvantage of this approach is that simulation time is wasted while waiting for steady-state conditions to be achieved.

In the present study, it was decided to use a combination of the two methods. Appropriate initialisation conditions were used where possible; for example the model was set up so that wards were not empty at the beginning of each simulation run but instead contained a typical number of patients. However, pilot model runs indicated that some time had to elapse before the mean length of stay increased to its steady-state value and the U-MAE rate stabilised. A suitable run-in time was therefore determined by plotting the percentage U-MAE rate against time during twenty-five replications, and identifying visually the approximate point at which steady-state conditions had been reached in each. Figures 6.1 and 6.2 show the output from four replications for each simulated ward. It has been recommended that the moving average is used to determine the run-in time (Law and Kelton, 1991), however the U-MAE rate was used in the present case as this required no additional calculation. The U-MAE rate is a cumulative value and its use is therefore likely to result in a run-in time in excess of that determined using moving averages. The behaviour of the mean ward length of stay was also examined as this took some time to achieve steady-state and was a key input that affected the U-MAE rate (figures 6.3 and 6.4). A run-in time of 1680 hours (10 weeks) was thus selected, during which no data were collected from the model.

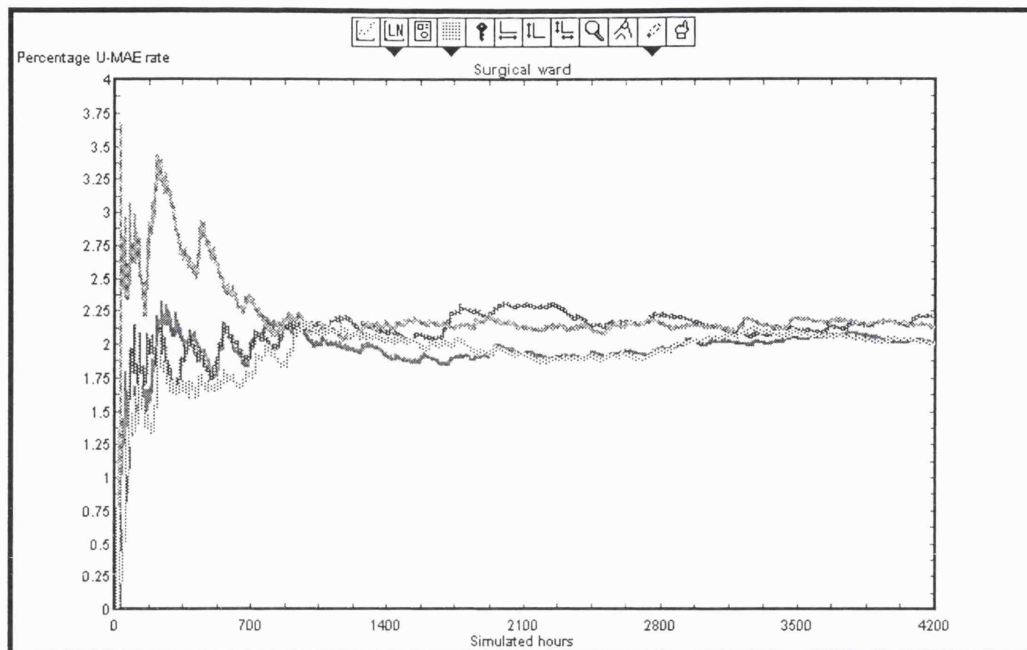


Figure 6.1 Surgical ward base case configuration: four replications showing how the predicted U-MAE rate fluctuates at the beginning of the simulation.

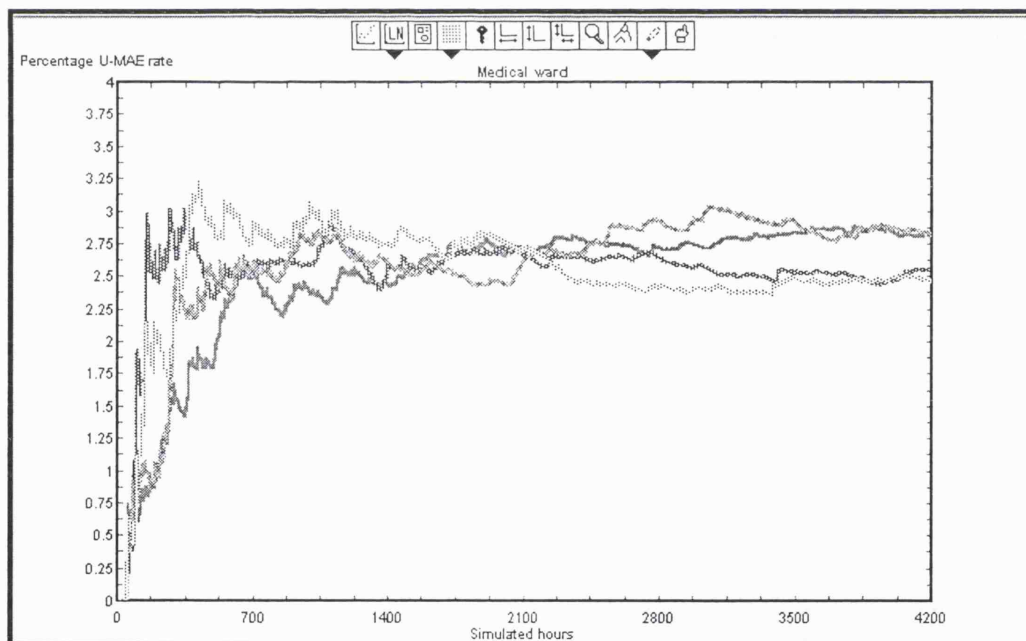


Figure 6.2 Medical ward base case configuration: four replications showing how the predicted U-MAE rate fluctuates at the beginning of the simulation.

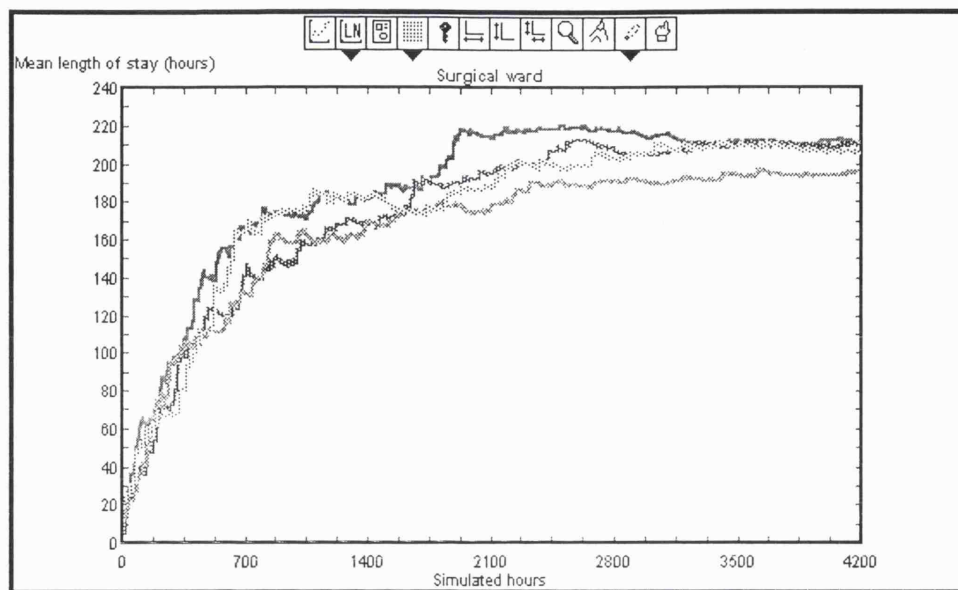


Figure 6.3 Surgical ward base case configuration: four replications showing how the mean length of stay takes time to increase to its steady-state value.

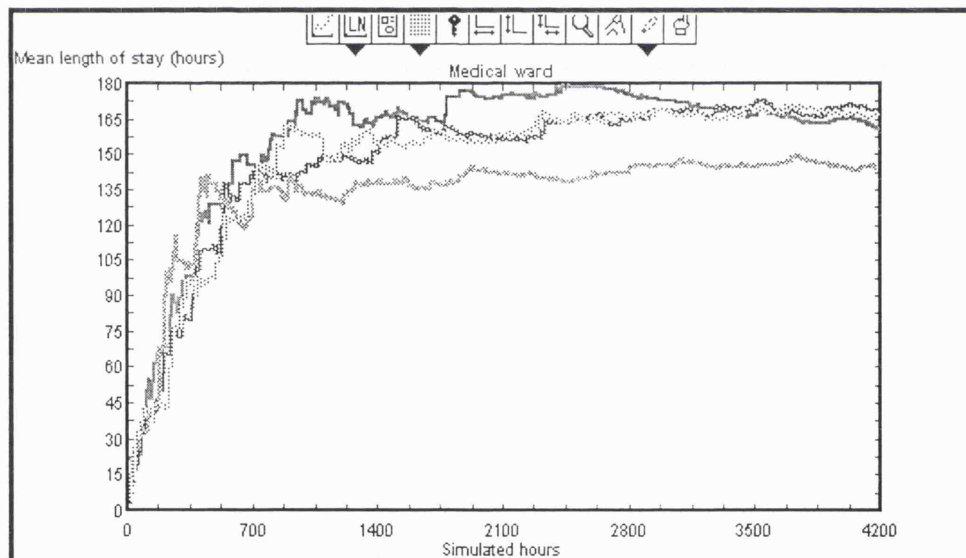


Figure 6.4 Medical ward base case configuration: four replications showing how the mean length of stay takes time to increase to its steady-state value.

6.3.2 Independent replications versus batching

Since each replication of a stochastic simulation provides only an estimate of the model's true characteristics, multiple samples are generally required to increase the accuracy with which predictions are made. Two methods can be used to obtain multiple samples. The first involves making independent replications of the simulation, using a different stream of random numbers for each replication. The second involves making a very long simulation run and dividing the results into batches, each of which is then considered to be one sample (Law and Kelton, 1991). This method of batching has been recommended for use in non-terminating simulations, as only one run-in period is required and the total simulation time therefore reduced (Oakshott, 1997). The main disadvantage of batching is that many systems exhibit auto-correlation and successive samples may not be independent. Since most statistical tests require samples of data to be independent, such auto-correlation results in analytical problems. To investigate the extent to which auto-correlation existed in the present case, a 25-week simulation run was made for each simulated ward. The percentage U-MAE rate was calculated for each simulated week, and the U-MAE rate for each week plotted against the U-MAE rate for the following week (Law and Kelton, 1991). As shown in figures 6.5 and 6.6, there was no identifiable auto-correlation. However, in the present study, the delay in achieving steady-state conditions was partly due to fluctuations in the calculated U-MAE rate at low sample sizes; each batch would therefore have to be of at least ten weeks to allow the calculated U-MAE rate to stabilise at its steady-state value. Since some time must also elapse between successive batches, the method of batched means was considered to have little advantage over independent replications in this case. It was therefore decided to make independent replications of each model configuration.

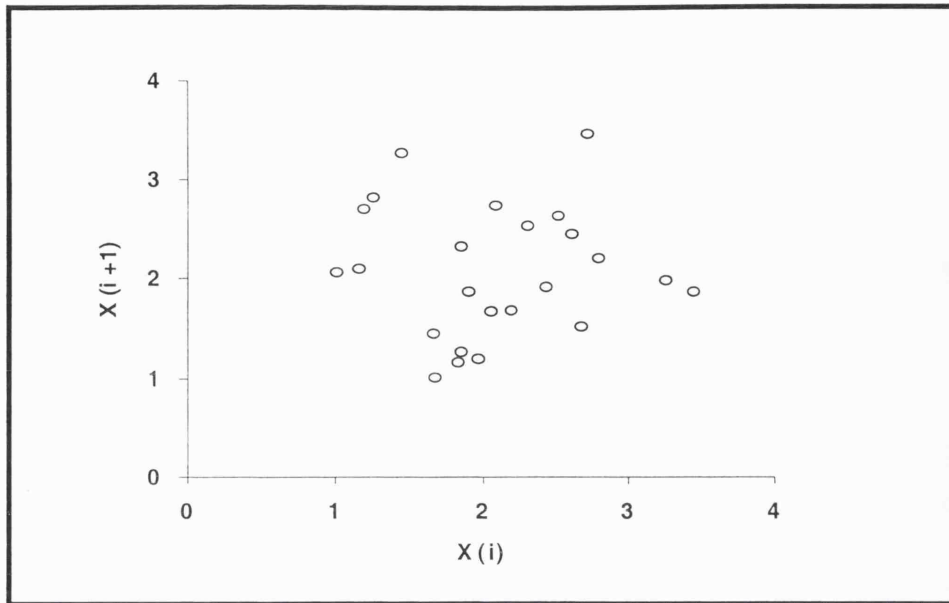


Figure 6.5 Surgical ward base case configuration: auto-correlation plot. Graph shows percentage U-MAE rate for a given week $[X(i)]$ plotted against the percentage U-MAE rate for the following week $[X(i+1)]$. $R^2 < 0.0001$ (Pearson's correlation coefficient); $n = 25$ weeks.

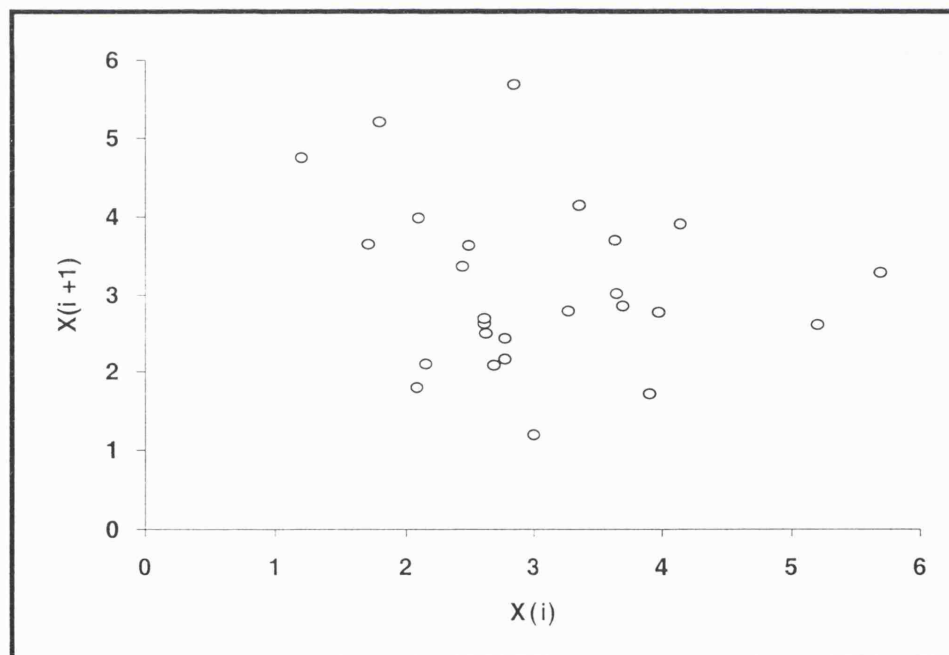


Figure 6.6 Medical ward base case configuration: auto-correlation plot. Graph shows percentage U-MAE rate for a given week $[X(i)]$ plotted against the percentage U-MAE rate for the following week $[X(i+1)]$. $R^2 = 0.008$ (Pearson's correlation coefficient); $n = 25$ weeks.

6.3.3 Length of each simulation run

To increase the validity of the results obtained, it is generally recommended that each replication is much longer than the warm-up time (Law and Kelton, 1991; Banks *et al*, 1996). However, the meaning of ‘much longer’ is not made explicit. To determine the most efficient run length for the present study, twenty-five replications were made, each of 16800 simulated hours (100 weeks), to identify the approximate point beyond which the mean U-MAE rate remained constant (figures 6.7 and 6.8). It was found that the mean U-MAE rate stabilised after about 2500 simulated hours, but its standard deviation progressively decreased with increased simulation time. Since the standard deviation decreased most dramatically during the first 3500 simulated hours, a total run length of 4200 hours (25 weeks) was selected, which included a 1680 hour (10 week) run-in time.

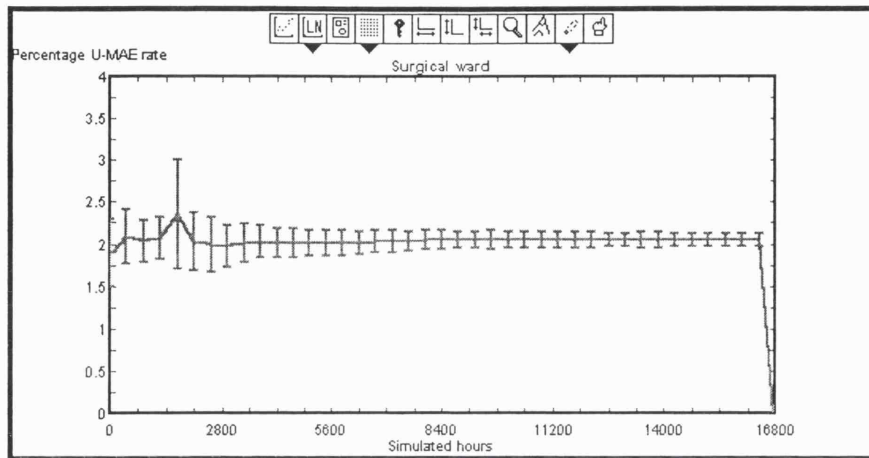


Figure 6.7 Surgical ward base case configuration: the effect of increasing the length of each simulation run.

Figure shows mean U-MAE rate for 25 replications, each of 16800 hours. Error bars represent standard deviations.

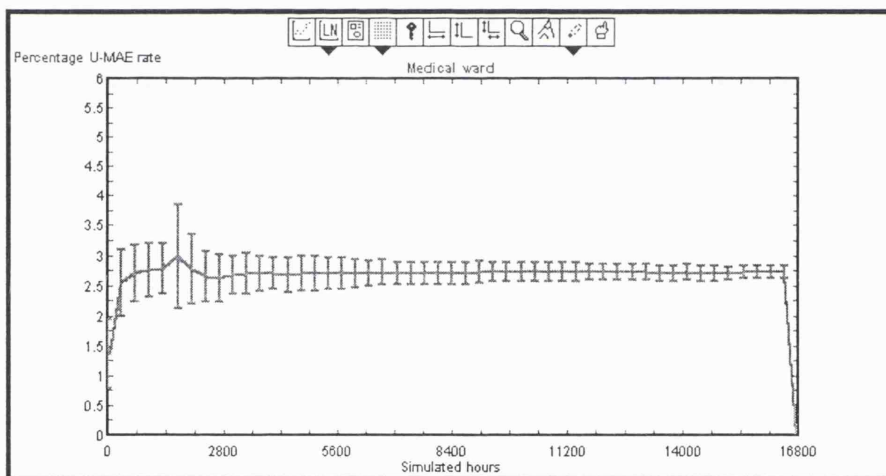


Figure 6.8 Medical ward base case configuration: the effect of increasing the length of each simulation run.

Figure shows mean U-MAE rate for 25 replications, each of 16800 hours. Error bars represent standard deviations.

6.3.4 Number of replications

If a mean value is calculated from the results of multiple replications, its associated confidence interval narrows as the number of replications increases (Pidd, 1998). However, since the confidence interval is proportional to the reciprocal of the square root of the sample size; this convergence is rapid initially but declines with continued replication. It has been suggested that the most efficient number of replications is usually about 25 (Banks *et al*, 1996). To determine whether this was the case in the present study, forty independent replications were made for each simulated ward and the 95% confidence interval half-width for the mean U-MAE rate plotted after each additional replication (figures 6.9 and 6.10). It was confirmed that increasing the number of replications to more than 25 would have comparatively little effect on the width of the confidence interval; it was therefore decided to make 25 replications of each configuration in the present study.

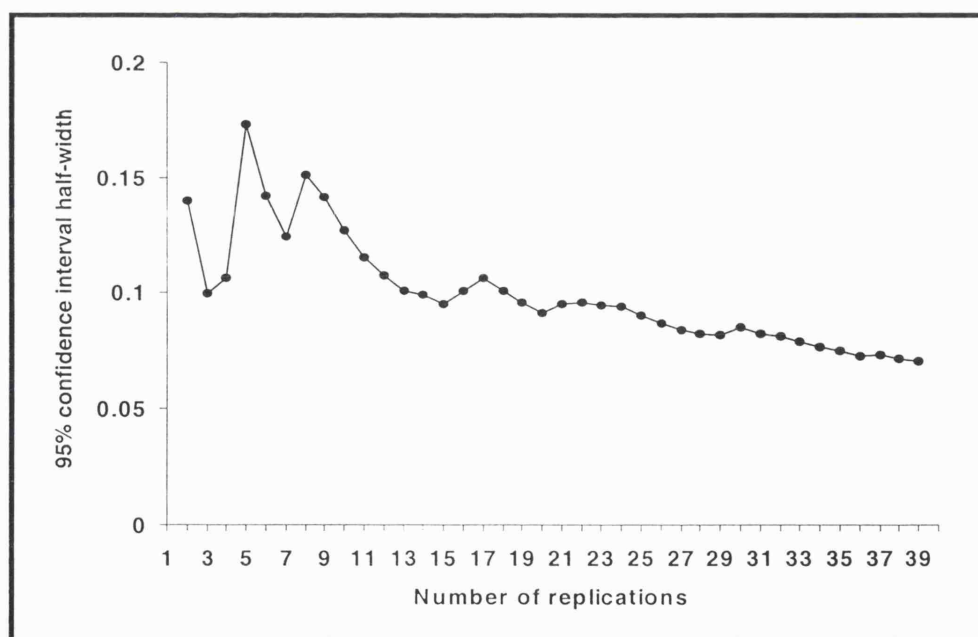


Figure 6.9 Surgical ward base case configuration: the effect on the 95% confidence interval half-width of increasing the number of replications (each of 25 weeks duration).

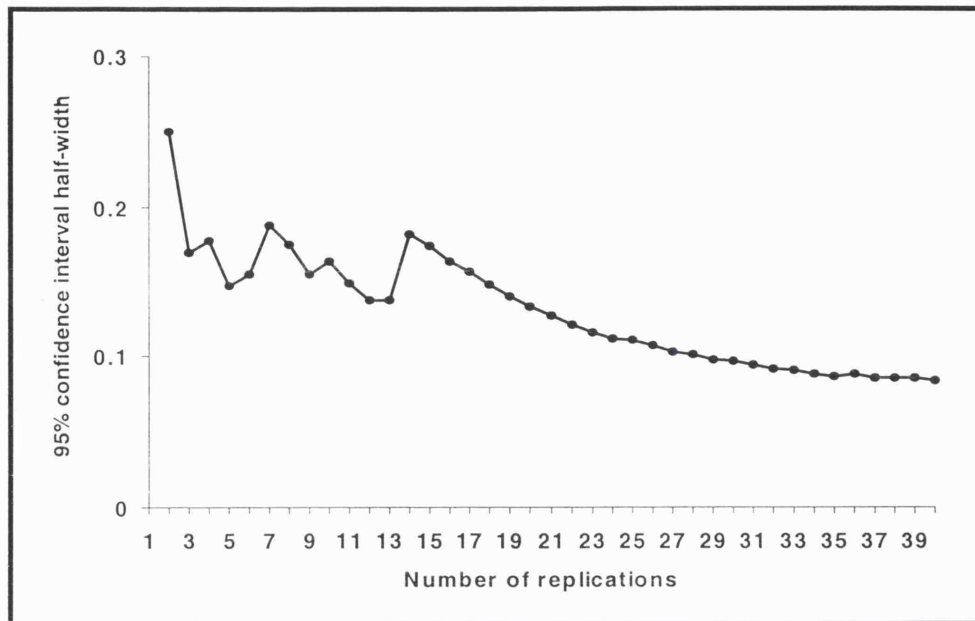


Figure 6.10 Medical ward base case configuration: the effect on the 95% confidence interval half-width of increasing the number of replications (each of 25 weeks duration).

6.3.5 Variance reduction

The response variables of stochastic simulations often display relatively large variance, resulting in wide confidence intervals around estimated mean values. As discussed in section 6.3.4, increasing the number of replications increases the precision of the estimates, but additional methods for reducing variance also exist (Pidd, 1998). Of these, the method of common random numbers is the most widely used. This approach involves simulating alternative system configurations using the same streams of random numbers for each configuration. Any differences in the results obtained will therefore be due to the different system configurations, rather than to differences in the random numbers used. Other variance reduction techniques such as antithetic sampling (in which pairs of replications of the same system configuration are designed to be negatively correlated) are more complicated to carry out and if not used properly, can increase the variance (Law and Kelton, 1991; Pidd, 1998). It was therefore decided to investigate the use of common

random numbers as a potential variance reduction technique for the present study.

6.3.5.1 The effect of using common random numbers

To test the effect of using common random numbers, 25 replications were made for each base-case configuration and two examples of alternative configurations, using common random numbers. The two alternative configurations tested were a system in which patients use supplies of their own medication while in hospital, and the introduction of computerised prescribing. These drug distribution systems will be described in more detail in section 6.4. For each of the 25 replications, the difference between the base case and the alternative configuration U-MAE rate was calculated. The variance of these differences was then calculated; this is the variance using the method of common random numbers. The variance obtained without using common random numbers was also calculated (Law and Kelton, 1991). Table 6.1 shows that using common random numbers dramatically reduced the variance of the differences between the configurations. It was therefore decided to adopt this approach in the present study.

Ward	System compared with base case	σ^2 without CRN	σ^2 with CRN
Surgical	Patients' own drugs	0.039*	0.006
Surgical	Computerised prescribing	0.043	0.010
Medical	Patients' own drugs	0.119	0.011
Medical	Computerised prescribing	0.124	0.068

Table 6.1 The effect of using common random numbers.

* Figures show variance (σ^2) of the differences between the base case and alternative system percentage U-MAE rates, with and without using common random numbers (CRN).

6.3.6 Statistical analysis

As previously discussed, the results obtained from each run of a stochastic simulation represent only samples from a wider population and appropriate statistical tests are

therefore required for their analysis.

The objective of the statistical analysis was to determine which alternative drug distribution systems resulted in U-MAE rates that were significantly different from the base case U-MAE rate. To determine whether parametric tests were appropriate for this purpose, the U-MAE rates for forty independent simulations of each base case configuration were plotted and compared to a normal distribution. Hypotheses that the output values were normally distributed could not be rejected (figures 6.11 and 6.12) and parametric tests therefore adopted.

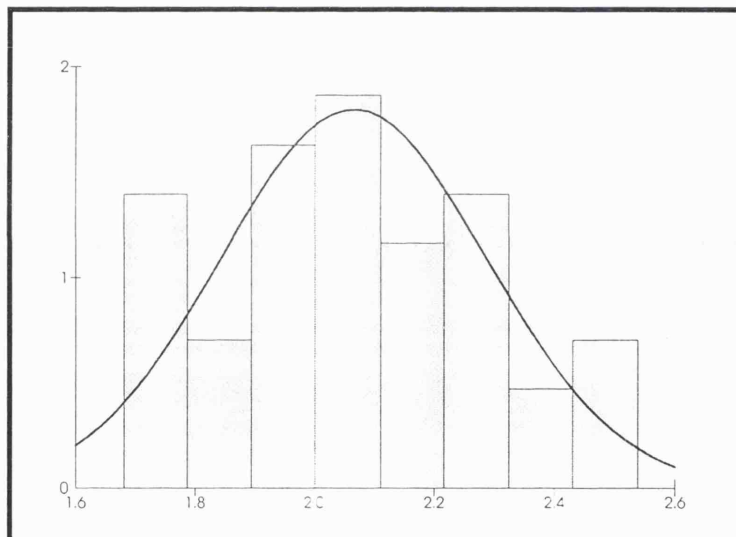


Figure 6.11 Surgical ward base case configuration: percentage U-MAE rates for 40 independent replications (grey bars), compared with the normal (2.07, 0.22) distribution (black line); $p > 0.15$ (Kolmogorov-Smirnov test).

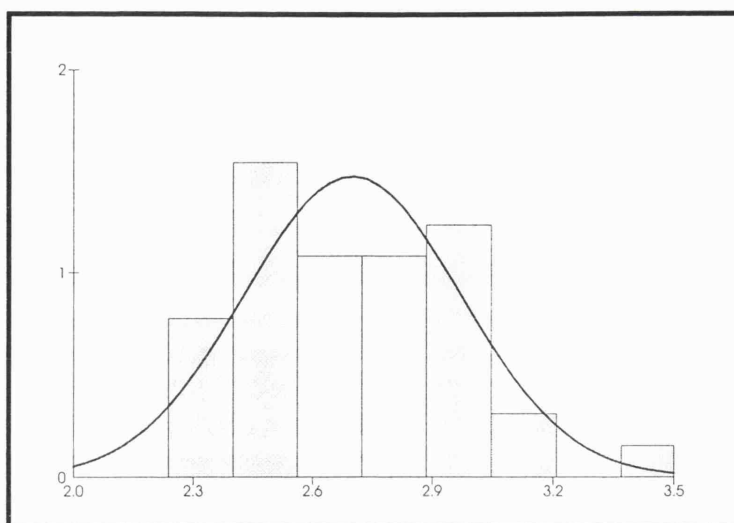


Figure 6.12 Medical ward base case configuration: percentage U-MAE rates for 40 independent replications (grey bars), compared with the normal (2.70, 0.27) distribution (black line); $p > 0.15$ Kolmogorov-Smirnov test.

Since common random numbers were used, identical samples of simulated patients were admitted and discharged for each system configuration. Confidence intervals for the difference between each alternative drug distribution system U-MAE rate and the base case U-MAE rate were therefore calculated using the method based on paired-sample t-tests (Oakshott, 1997).

In the next section, the alternative drug distribution systems tested using the model will be described.

6.4 Alternative drug distribution systems

Although the options that could be explored using the model were almost infinite, a number of relatively straightforward changes to the drug distribution system were chosen for investigation in the present study. These options are summarised in figure 6.13 and described in more detail below.

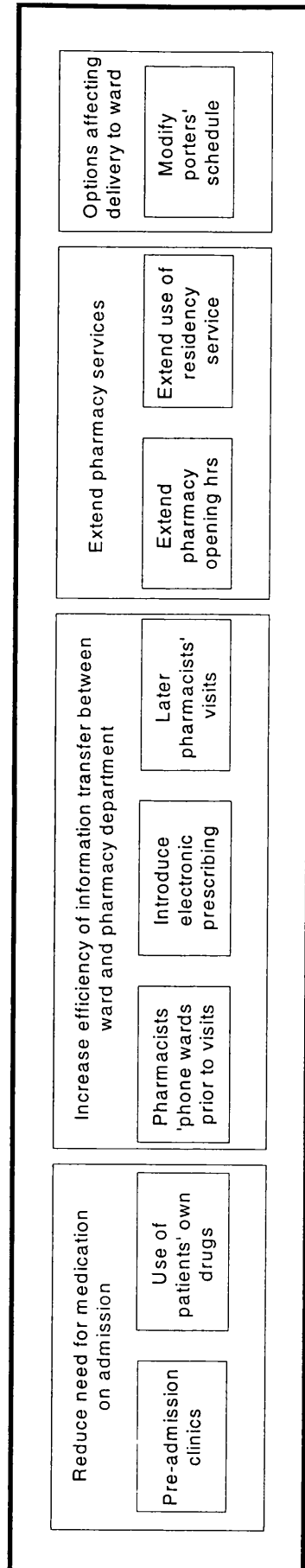


Figure 6.13 Potential options for changing the drug distribution system, with the aim of reducing U-MAEs.

6.4.1 Options to reduce the need for individually dispensed medication following admission

6.4.1.1 Introduction of pre-admission clinics

This option involves the introduction of pre-admission clinics that would be attended by all patients with planned hospital admissions. At these clinics, medication histories would be taken and drug charts written, so that any non-stock medication required could be dispensed and delivered to the ward in advance of the patient's admission (Bhanji *et al*, 1993; Cousins and Luscombe, 1996). To simulate this system, it was assumed that 40% of patients on each study ward have planned admissions (table 4.3) and that all of these patients would attend the pre-admission clinic. It was also assumed that all medication orders for drugs taken prior to the patient's admission would be written at the clinic and thus supplied before the patient was admitted.

6.4.1.2 Use of patients' own drugs

Several UK hospitals are implementing a system in which patients' own medication is stored in individual medicines cabinets and used during their hospital stay (Ashcroft *et al*, 1995; Semple *et al*, 1995; John, 1997). However, the effect of this system on MAEs has not yet been considered. To simulate this system, it was assumed that 50% of patients would bring to hospital a supply of any drugs that they were taking prior to admission, that sufficient medication would be brought into hospital for the duration of the patient's stay and that all supplies would be suitable for use. A figure of 50% was selected as this was the median percentage of patients reported to bring in their own drugs in published studies (Horner and Lochery, 1990; Thomas *et al*, 1991; Robinson, 1993; Ashcroft *et al*, 1995; Semple *et al*, 1995).

6.4.2 Options to increase the efficiency of information transfer between ward and pharmacy

6.4.2.1 Pharmacists telephoning wards prior to each visit

In this system, pharmacists would telephone their wards immediately prior to each

scheduled ward visit to obtain details of any unsupplied medication orders. Any medication required would then be dispensed and taken immediately to the ward, where the original prescription would be checked and signed. It was assumed that the pharmacists' visits would have the same times and durations as in the base case system, and that the pharmacists would be given details by telephone of all unavailable non-stock medication.

6.4.2.2 Introduction of electronic prescribing

This option involves the introduction of a computerised prescribing or electronic mail system, so that medication orders would be transmitted to the pharmacy department immediately after they have been written (Jones and Horsley, 1997). It was assumed that dispensing times would be unaffected and that medication would be dispensed only during pharmacy opening hours, which would remain the same as in the base-case system.

6.4.2.3 Later pharmacists' visits

In this system, pharmacists would visit their wards at about 11 am and 3:30 pm instead of early in the morning and early in the afternoon. These times were chosen as the preliminary study described in section 3.6 suggested that later visits could increase the efficiency of the supply process. It was assumed that the distributions of visit times and durations would remain the same as in the base case.

6.4.3 Options to extend pharmacy services

6.4.3.1 Extend pharmacy opening hours

This option involves the extension of weekday pharmacy opening hours to 8 pm. It was assumed that if any new non-stock medication orders were identified during the 6 pm drug round, nursing staff would bring the relevant drug charts to the pharmacy department so that the medication could be dispensed. It was assumed that the medication required would be dispensed within one hour and that a member of ward staff would collect the dispensed medication and take it to the ward before 8 pm.

6.4.3.2 *Extend residency service*

Currently, although a 24-hour residency service exists at the study hospital, the resident on-call pharmacists are asked to supply only a small proportion of unavailable products (section 4.12). It was assumed that in an extended system, nursing staff would contact the resident pharmacist to request the supply of all new non-stock medication orders identified during the 6 pm and 10 pm drug rounds. Again, it was assumed that the medication required would be dispensed within one hour and that a member of ward staff would collect the dispensed medication as soon as it was ready.

6.4.4 Options affecting delivery to the ward

6.4.4.1 *Modify porters' delivery schedule*

This option involves the modification of the pharmacy porters' delivery times, so that the first porters' delivery would take place at 11 am instead of at noon and the last delivery at 5:00 pm instead of at 5:30 pm. These times were chosen so that dispensed medication would be delivered to the ward prior to the noon and 6 pm drug rounds.

Having selected a series of options for investigation, the next stage of the present study was to simulate each of these changes to the drug distribution system and examine the U-MAE rates predicted.

6.5 Simulation of the alternative drug distribution systems

6.5.1 Simulation methods

For the base case and each alternative drug distribution system, 25 replications of 4200 hours (25 weeks) were made using matched streams of random numbers. The first 1680 hours' (10 weeks) data were discarded during each replication and the predicted U-MAE rate calculated for the remaining 2520 hours (15 weeks).

Prior to each replication, initial conditions were set as shown in table 6.2.

Variable	Surgical ward	Medical ward
Patients on ward	26	15
Medication orders on existing patient's drug charts	130	105

Table 6.2 Initial conditions used for the simulation of each ward.

6.5.2 Statistical analysis

The mean predicted U-MAE rate and its standard deviation were calculated for each set of 25 replications; a confidence interval based on the matched-pairs t-test was calculated for the difference between each alternative drug distribution system and the base case. Since eight comparisons were being made for each ward, the use of 95% confidence intervals could result in about 40%¹ of statistically significant differences being spurious. In order to reduce the probability of such type I errors, 99% confidence intervals were calculated instead. This corresponds to an α (the probability of making a type I error) of 0.01 for each of the 8 comparisons made, or an overall α of about 0.08 for each simulated ward (Bryman and Cramer, 1997).

6.5.3 Results

Figures 6.14 and 6.15 summarise the results obtained; tables 6.3 and 6.4 give more detailed results. The base case U-MAE rates predicted were 2.06% and 2.66% for the surgical and medical wards respectively. If about 1000 doses are given per ward per week, these figures correspond to approximately 21 U-MAEs per week on the surgical ward and 27 on the medical ward.

¹ 0.05×8 , based on the Bonferroni correction.

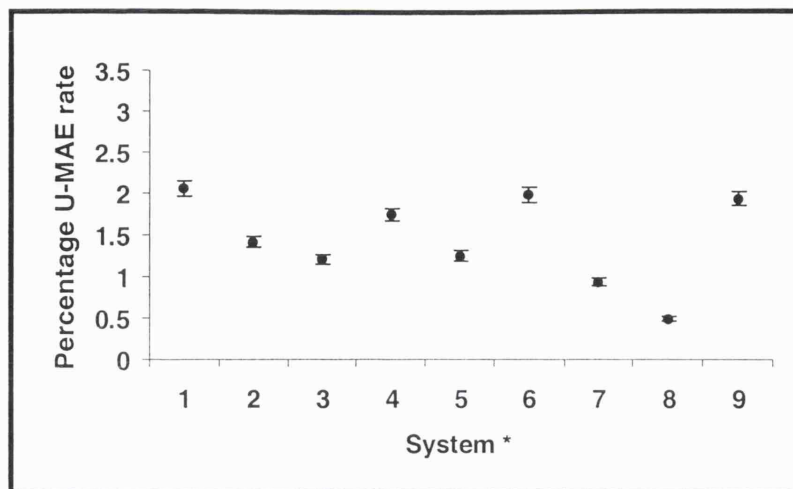


Figure 6.14 Surgical ward: U-MAE rate predicted for each system. Error bars show 95% confidence intervals.

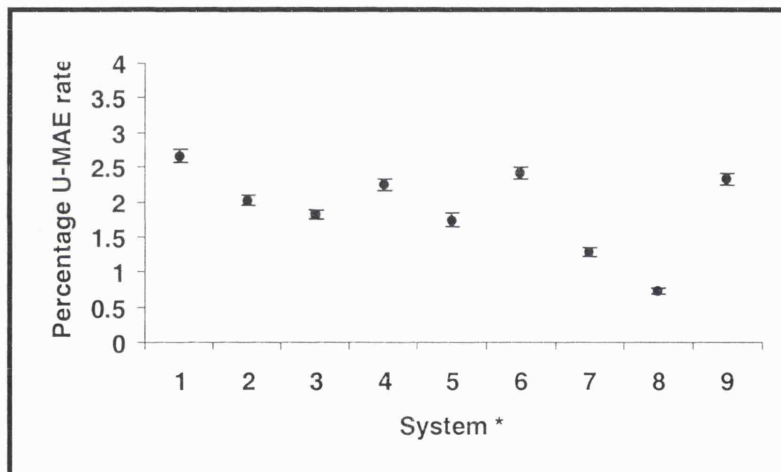


Figure 6.15 Medical ward: U-MAE rate predicted for each system. Error bars show 95% confidence intervals.

* 1: traditional ward pharmacy system (base case)

2: pre-admission clinics

3: use of patients' own drugs

4: telephoning prior to visit

5: electronic prescribing

6: later pharmacists' visits

7: extended pharmacy hours

8: extended residency service

9: modified porters' schedule

All of the alternative drug distribution systems tested reduced the predicted U-MAE rate and all of these reductions were statistically significant. However, some of the reductions were relatively small and could not be considered clinically meaningful. It was therefore decided to select a difference that could be considered clinically meaningful as opposed to statistically significant; a reduction of at least 20% of the base case U-MAE rate was selected. This corresponds to reductions in the U-MAE rate of 0.41% and 0.53% for the surgical and medical wards respectively, or approximately five U-MAEs per week on each ward.

According to this criterion, clinically meaningful reductions in U-MAE rates were predicted on each simulated ward for the introduction of pre-admission clinics, the use of patients' own drugs, the introduction of electronic prescribing, the extension of pharmacy opening hours and the extension of the residency service. The relative benefits of each system were very similar on each ward; the results also suggest that the most dramatic benefits could be obtained by introducing relatively simple changes to pharmacy services.

Drug distribution system	Mean U-MAE rate*	SD †	Difference from base case	99% CI‡ for the difference
Base case	2.06%	0.23%	---	---
<i>Need for medication on ward</i>				
Pre-admission clinics	1.41%	0.16%	- 0.65%	- 0.71 to - 0.60%
Use patients' own drugs	1.21%	0.14%	- 0.85%	- 0.92 to - 0.79%
<i>Information transfer between ward and pharmacy department</i>				
Telephoning prior to visit	1.74%	0.19%	- 0.33%	- 0.35 to - 0.30%
Electronic prescribing	1.25%	0.16%	- 0.81%	- 0.89 to - 0.73%
Later pharmacists' visits	1.98%	0.25%	- 0.09%	- 0.13 to - 0.04%
<i>Extend pharmacy services</i>				
Extend opening hours	0.93%	0.11%	- 1.14%	- 1.22 to - 1.05%
Extend residency service	0.49%	0.06%	- 1.57%	- 1.67 to - 1.47%
<i>Delivery to ward</i>				
Modify porters' schedule	1.93%	0.22%	- 0.13%	- 0.15 to - 0.12%

Table 6.3 Results of simulation experiments for the surgical ward.

Values are reported only to 2 decimal places; bold entries refer to clinically meaningful reductions from the base case U-MAE rate.

* Mean of the 25 replications.

† SD: Standard deviation for the 25 replications.

‡ CI: Confidence interval for the difference between each alternative drug distribution system and the base case.

Drug distribution system	Mean U-MAE rate [*]	SD [†]	Difference from base case	99% CI [‡] for the difference
Base case	2.66%	0.25%	---	---
<i>Need for medication on ward</i>				
Pre-admission clinics	2.02%	0.21%	- 0.64%	- 0.70 to - 0.58%
Use patients' own drugs	1.82%	0.18%	- 0.84%	- 0.90 to - 0.79%
<i>Information transfer between ward and pharmacy department</i>				
Telephoning prior to visit	2.24%	0.21%	- 0.42%	- 0.54 to - 0.30%
Electronic prescribing	1.74%	0.23%	- 0.92%	- 1.06 to - 0.80%
Later pharmacists' visits	2.42%	0.23%	- 0.24%	- 0.28 to - 0.20%
<i>Extend pharmacy services</i>				
Extend opening hours	1.28%	0.18%	- 1.38%	- 1.48 to - 1.28%
Extend residency service	0.73%	0.10%	- 1.94%	- 2.05 to - 1.83%
<i>Delivery to ward</i>				
Modify porters' schedule	2.34%	0.22%	- 0.32%	- 0.35 to - 0.30%

Table 6.4 Results of simulation experiments for the medical ward.

Values are reported only to 2 decimal places; bold entries refer to clinically meaningful reductions from the base case U-MAE rate.

^{*} Mean of the 25 replications.

[†] SD: Standard deviation for the 25 replications.

[‡] CI: Confidence interval for the difference between each alternative drug distribution system and the base case.

6.6 Sensitivity analysis

Many assumptions were made regarding the data used as model inputs, as discussed in Chapter Four. To explore the effects of these assumptions on the model's results, it was necessary to carry out a sensitivity analysis. This took place in two stages. In the first stage, simulations of the base-case drug distribution system were repeated for each ward, varying one input parameter at a time. This was considered a screening stage to identify those inputs to which the output was most sensitive. In the second stage, simulations of the most promising alternative drug distribution systems were repeated using different values for each sensitive parameter; this was to explore the robustness of the results obtained and to find out whether the overall conclusions were affected by changes in the input parameters. These two stages will be considered in turn.

6.6.1 Sensitivity analysis stage one: Identification of input parameters to which the output is sensitive

6.6.1.1 Methods

Input variables investigated

Variables investigated in the first stage of the sensitivity analysis were as follows:

1. Patient admission times

The distributions used to generate simulated patient admissions in the model were developed using only fourteen days' real world data (section 4.7). Furthermore, on the medical ward it was assumed that numbers of admissions were equal on Mondays to Fridays although this was not the case in practice. To explore the importance of any such imprecision, it was decided to repeat the simulation for each study ward using the distribution of patient admission times determined for the other ward.

2. Ward length of stay distributions

Exponential distributions were chosen to represent ward length of stay data, in spite of

goodness-of-fit tests suggesting that these did not adequately fit the data concerned (section 4.8). It was therefore decided to repeat the simulations using a different distribution to represent the ward lengths of stay. Since the main problem associated with the exponential distribution was that it over-represented very short lengths of stay, the lognormal distribution, which under-represented very short lengths of stay, was investigated in the sensitivity analysis. The lognormal (221, 304) and lognormal (161, 249) distributions were tested for the surgical and medical wards respectively; these were the lognormal distributions that most closely corresponded to the real world length of stay data. It was also decided to explore the effects of increasing and decreasing the mean length of stay. Exponential distributions with mean values one day longer and one day shorter than the base case values were therefore tested for each simulated ward.

3. Numbers of medication orders written per patient on admission

The distributions describing the numbers of medication orders written per patient on admission were estimated from only fourteen days' data (section 4.5). For each ward, the distribution selected for the other ward was therefore tested during the sensitivity analysis.

4. Times at which medication orders are written for existing patients

The times of medication order writing for existing patients were also estimated from only fourteen days' data (section 4.5). Again, it was decided to repeat the simulations for each study ward using the distribution determined for the other ward.

5. Percentage of medication orders that are for ward stock drugs

In the base case configuration, about 70% of all medication orders were considered to be stock on each ward; it was therefore decided to explore the effects of using figures of 60% and 80%. These values are just outside the 95% confidence intervals that were calculated for the percentage of doses that are stock on each study ward (section 4.6.5.2).

6. Percentage of medication orders that are for drugs taken prior to admission

During the sensitivity analyses, the effects of a ten percent increase and a ten percent decrease in the proportion of drugs taken prior to admission were explored. Again, these

values were just outside the 95% confidence intervals calculated for this parameter for each study ward (section 4.6.5.1).

7. Dose regimes of the drugs prescribed

For each ward, the importance of this input parameter was investigated by using the distribution determined for the other ward.

8. Times of ward pharmacists' visits

The times of the ward pharmacists' visits were determined from only fourteen days' data (section 4.9); it was therefore decided to perform a sensitivity analysis using mean morning visit times half an hour earlier and half an hour later than those used in the base case analysis. The majority of medication orders are supplied following the morning ward pharmacist's visit; it was therefore considered less important to explore the effects of varying the times of the afternoon visits.

9. Durations of ward pharmacists' visits

The effects of increasing and decreasing the durations of the ward pharmacists' morning visits were explored. The base case mean durations were 0.90 hours and 0.55 hours on the surgical and medical wards respectively; durations of 0.5 hours and 1.5 hours were therefore investigated on the surgical ward and durations of 0.25 hours and 1 hour on the medical ward.

10. Dispensing times

Real world dispensing times varied with the number of drugs on the ward pharmacy order form and the time at which the ward pharmacy order form was delivered to the dispensary; however this was not taken into account in the model (section 4.10). The mean dispensing time used in the model was about one hour; it was therefore decided to explore the effects of using mean dispensing times of thirty and ninety minutes during the sensitivity analysis.

11. Time taken for porters to deliver medication to ward

The time taken for the porters to deliver dispensed medication to the wards was estimated by the porters to be thirty minutes (section 4.11). Given the possible imprecision in this estimate, durations of fifteen and forty-five minutes were also tested.

Simulation methods

For each of the alternatives investigated, 25 replications were made using common random numbers, in an identical manner to that described in section 6.5.1.

Statistical analysis

The mean U-MAE rate for each alternative was compared with the base case U-MAE rate and the 99% confidence interval for the difference calculated. Since 19 comparisons were being made, this is equivalent to using an overall α of 0.19 for each simulated ward. However in the sensitivity analysis, it was considered more important to avoid making type 2 errors (concluding that there is no difference when one exists) than type 1 errors (concluding that there is a difference when none exists) and a large value of α was therefore considered appropriate.

Since common random numbers were used, confidence intervals based on the matched-pairs t-test could be used for the majority of comparisons. However, in four cases the sensitivity analysis involved changing patient admission times; in these cases confidence intervals based on the matched-pairs t-test could not be used. These four were the use of a lognormal length of stay distribution, use of shorter and longer mean lengths of stay and using different distributions for the times at which patients are admitted. In these cases, confidence intervals were calculated using the method recommended for large samples, based on the normal distribution (Swinscow and Campbell, 1996).

6.6.1.2 Results

The results of the first stage of the sensitivity analysis are shown in tables 6.5 and 6.6. As with the comparison of the different drug distribution systems, the calculated confidence

intervals were very narrow and very small differences between the base case and alternative configurations were therefore statistically significant. It was again decided to select a difference that could be considered clinically meaningful as opposed to statistically significant. For the purposes of this screening stage, this was taken to be an increase or decrease in the mean U-MAE rate of more than 10% of the base case U-MAE rate. The differences taken as being meaningful were therefore 0.21% for the surgical ward and 0.27% for the medical ward. To ensure that all sensitive parameters were identified, any alternative configurations for which the 99% confidence interval included these values were selected for inclusion in the second stage of the sensitivity analysis.

For the surgical ward, meaningful differences were identified for different mean lengths of stay, the use of a different distribution to represent the times at which medication orders are written for existing patients, changing the percentage of stock drugs and changing the percentage of medication orders that are for drugs taken prior to the patient's admission.

On the medical ward, meaningful differences were identified for the use of a different distribution of patient admission times, different mean lengths of stay, the use of a different distribution to represent numbers of medication orders written per patient on admission and the percentage of medication orders that are for stock drugs.

The proportion of medication orders that were for drugs taken by the patient prior to their admission had a significant effect on the simulation results for the surgical ward but not for the medical ward. This difference was because on the surgical ward, drugs that were not taken prior to the patient's admission were much more likely to be ward stock than drugs that were taken prior to admission (figure 4.1). This difference is less dramatic on the medical ward (figure 4.2). However, because the effect of changing the value of this variable is related to the effect of changing the percentage of stock drugs, it was decided to examine only the effect of changing the proportion of stock drugs in the next stage of the sensitivity analysis.

Configuration	Mean U-MAE rate	SD *	Difference from base case	99% CI † for the difference
Base case	2.06%	0.23%	---	---
<i>Patient admission times</i>				
Medical ward's distribution	2.04%	0.27%	- 0.02%	- 0.20 to + 0.16%
<i>Length of stay</i>				
One day longer	1.89%	0.23%	- 0.17%	- 0.34 to - 0.01%
One day shorter	2.33%	0.19%	+ 0.26%	+ 0.11 to + 0.42%
Lognormal distribution	2.08%	0.22%	+ 0.02%	- 0.15 to + 0.18%
<i>Medication orders written per patient on admission</i>				
Medical ward's distribution	2.15%	0.17%	+ 0.09%	+ 0.00 to + 0.18%
<i>Times at which medication orders written for existing patients</i>				
Medical ward's distribution	1.74%	0.18%	- 0.33%	- 0.41 to - 0.24%
<i>Characteristics of the drugs prescribed</i>				
60% stock	2.64%	0.25%	+ 0.58%	+ 0.53 to + 0.63%
80% stock	1.29%	0.14%	- 0.77%	- 0.84 to - 0.71%
10% decrease in PRIOR‡	1.90%	0.21%	- 0.16%	- 0.23 to - 0.10%
10% increase in PRIOR‡	2.21%	0.23%	+ 0.15%	+ 0.08 to + 0.21%
Medical ward dose regimes	2.12%	0.23%	+ 0.06%	+ 0.05 to + 0.07%
<i>Ward pharmacist's visits</i>				
Morning visit 0.5hr earlier	2.06%	0.23%	- 0.01%	- 0.02 to + 0.01%
Morning visit 0.5hr later	2.08%	0.24%	+ 0.02%	- 0.01 to + 0.04%
Morning visit 0.5hr duration	2.06%	0.23%	- 0.01%	- 0.02 to + 0.01%
Morning visit 1.5hr duration	2.09%	0.24%	+ 0.03%	+ 0.01 to +0.05%
<i>Dispensing</i>				
Mean dispensing delay 0.5hr	2.05%	0.23%	- 0.01%	- 0.02 to 0.00%
Mean dispensing delay 1.5hr	2.07%	0.23%	+ 0.01%	0.00 to + 0.02
<i>Porters' deliveries</i>				
Delay of 0.25hr	2.04%	0.23%	- 0.02%	- 0.03 to - 0.02%
Delay of 0.75hr	2.07%	0.23%	+ 0.00%	0.00 to + 0.01%

Table 6.5 Results of sensitivity analysis (stage 1) for the surgical ward.

Bold type indicates clinically meaningful differences.

* SD: Standard deviation for the 25 replications;

† CI: Confidence interval for the difference between each configuration and base case.

‡ PRIOR: Percentage of medication orders that are for drugs that the patient was taking prior to their admission.

Configuration	Mean U-MAE rate	SD *	Difference from base case	99% CI [†] for the difference
Base case	2.66%	0.25%	---	---
<i>Patient admission times</i>				
Surgical ward's distribution	2.81%	0.31%	+ 0.15%	- 0.06 to +0.35%
<i>Length of stay</i>				
One day longer	2.33%	0.25%	- 0.33%	- 0.51 to - 0.15%
One day shorter	3.02%	0.30%	+ 0.35%	+ 0.15 to + 0.55%
Lognormal distribution	2.63%	0.31%	- 0.03%	- 0.23 to + 0.18%
<i>Medication orders written per patient on admission</i>				
Surgical ward's distribution	2.99%	0.39%	+ 0.32%	+ 0.16 to + 0.48%
<i>Times at which medication orders written for existing patients</i>				
Surgical ward's distribution	2.90%	0.27%	+ 0.23%	+ 0.14 to + 0.32%
<i>Characteristics of the drugs prescribed</i>				
60% stock	3.72%	0.32%	+ 1.06%	+ 0.98 to + 1.14%
80% stock	1.85%	0.21%	- 1.82%	- 0.76 to - 0.87%
10% decrease in PRIOR [‡]	2.67%	0.26%	- 0.01%	- 0.10 to + 0.9%
10% increase in PRIOR [‡]	2.67%	0.28%	+ 0.01%	- 0.11 to + 0.13%
Surgical ward dose regimes	2.50%	0.24%	- 0.17%	- 0.18 to - 0.15%
<i>Ward pharmacist's visits</i>				
Morning visit 0.5hr earlier	2.67%	0.25%	+ 0.01%	0.00 to + 0.02%
Morning visit 0.5hr later	2.65%	0.25%	- 0.02%	- 0.01 to - 0.03
Morning visit 0.25hr duration	2.67%	0.25%	+ 0.01%	0.00 to + 0.02%
Morning visit 1.0hr duration	2.67%	0.25%	0.00%	0.00 to + 0.01%
<i>Dispensing</i>				
Mean dispensing delay 0.5hr	2.65%	0.25%	- 0.01%	0.00 to - 0.02%
Mean dispensing delay 1.5hr	2.67%	0.25%	+ 0.01%	+ 0.01 to + 0.02%
<i>Porters' deliveries</i>				
Delay of 0.25hr	2.64%	0.25%	- 0.02%	- 0.01 to - 0.02%
Delay of 0.75hr	2.67%	0.25%	0.00%	0.00 to + 0.01%

Table 6.6 Results of sensitivity analysis (stage 1) for the medical ward.

Bold type indicates clinically meaningful differences.

* SD: Standard deviation for the 25 replications;

† CI: Confidence interval for the difference between each configuration and base case.

‡ PRIOR: Percentage of medication orders that are for drugs that the patient was taking prior to their admission.

It was concluded that the mean length of stay, the distribution describing the times at which medication orders are written for existing patients and the percentage of medication orders that are for stock drugs should be taken into account for each ward during the next stage of the sensitivity analysis. For the medical ward, the distribution describing the numbers of medication orders written per patient on admission should also be investigated, and for the surgical ward the times at which patients are admitted.

6.6.2 Sensitivity analysis stage two: comparison of the different drug distribution systems

6.6.2.1 Methods

Simulations of the five most promising alternative drug distribution systems (the introduction of pre-admission clinics, the use of patients' own drugs, electronic prescribing, extended pharmacy hours and an extended residency service) were repeated, altering each sensitive parameter one at a time. This was to explore the robustness of the conclusions regarding the relative benefits of each system.

6.6.2.2 Results

Figures 6.16 and 6.17 give an example of the results obtained; the remainder are shown in Appendix 9. It was found that although altering the values of the input parameters affected the predicted U-MAE rates, the relative benefits of the five different drug distribution systems remained unaltered. It was therefore concluded that any inaccuracies in the input parameters used were unlikely to have affected the study's conclusions.

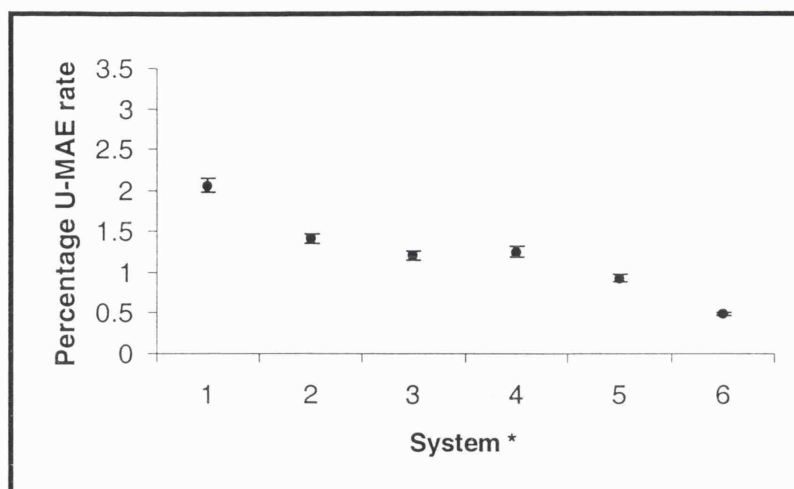


Figure 6.16 Surgical ward with base case parameters.
Error bars show 95% confidence intervals.

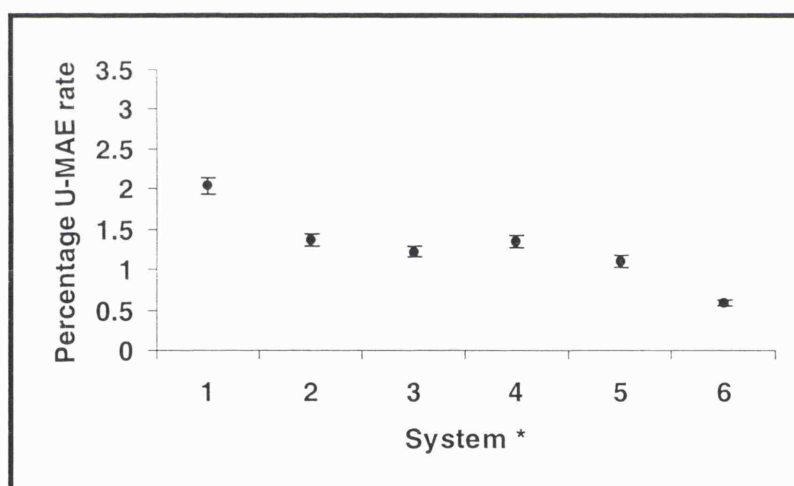


Figure 6.17 Surgical ward with medical admission times.
Error bars show 95% confidence intervals.

- *1: traditional ward pharmacy system (base case).
- 2: pre-admission clinics.
- 3: use of patients' own drugs.
- 4: electronic prescribing.
- 5: extended pharmacy opening hours
- 6: extended residency service.

6.7 Discussion

This study represents the first application of simulation modelling to the inpatient drug distribution system. A discrete-event simulation model was constructed and used to explore the effects on U-MAEs of different changes to the system. The results suggest that five of the eight drug distribution systems tested would decrease the U-MAE rate on each ward by a clinically meaningful amount. These were the introduction of pre-admission clinics, the use of patients' own drugs, the introduction of electronic prescribing, the extension of pharmacy opening hours and the extension of the residency service. The first two of these reduce the need for non-stock medication to be supplied following patient admission, computerised prescribing increases the speed of information transfer between ward and pharmacy, and the latter two involve the routine supply of non-stock medication during the evenings as well as during the day.

It was of particular interest that the most dramatic reductions in the U-MAE rate could be obtained by extending pharmacy opening hours or extending the scope of the residency service; both of these represent comparatively simple changes to existing pharmacy services. It was also found that the relative benefits of each change to the drug distribution system were similar on each simulated ward, although simulation of a wider range of wards would be required before it could be assumed that the benefits would be hospital-wide.

A sensitivity analysis was carried out to explore the robustness of the results obtained; it was concluded that simplifying assumptions made with respect to the model's inputs were unlikely to have affected the conclusions. It was also reassuring to find that the parameters to which the results were sensitive were those to which the real world U-MAE rate might be expected to be sensitive. During the sensitivity analysis, changes in mean ward length of stay were found to affect the predicted U-MAE rate; if ward length of stay is reduced, the predicted U-MAE rate increases. This finding could have important implications for today's hospitals, where improvements in technology are leading to reductions in the length of stay required for many hospital procedures.

Although a wide range of input parameters were investigated during the sensitivity analysis, it is recognised that there were many others that could have been studied. In particular, a sensitivity analysis could have been carried out to explore the impact of simplifying assumptions made regarding the structure and logic of the drug distribution system. However, such assumptions were generally made to reduce model complexity; to have tested their effects in a sensitivity analysis would have necessitated making a much more complex model. Another limitation of the sensitivity analysis carried out is that only one parameter was investigated at a time. Further work would be necessary to explore the effects of any interactions.

Additional simulation could be carried out to explore the results of this study in more detail. For example, during the simulation of extended pharmacy opening hours and the extended residency service, it was assumed that nurses would request supplies of all newly prescribed non-stock drugs that were unavailable during the evening drug round. However, it is possible that nurses would only notice that a drug was unavailable during those drug rounds for which doses of that drug were scheduled. This could be taken into account in further simulations.

The computerised prescribing system was modelled as though information was transmitted to the pharmacy department immediately after each medication order was written. However in some computerised prescribing systems there may be delays in this process. For example nurses or pharmacists may be required to enter medication orders into the computer system, or doctors' medication orders may require pharmacy validation before the medication concerned can be dispensed (Taxis, 1997). Additional simulations could explore the effects of using these types of system.

During the simulation of the pre-admission clinic system, it was assumed that the characteristics of the drugs prescribed for patients who attend pre-admission clinics would be similar to those prescribed for patients who do not. It is recognised that this may not be the case as elective and emergency admissions may be prescribed different types of drugs. Further data collection would be necessary in order to explore this issue.

The simulation model developed could also be used to explore a much wider range of potential changes to the hospital drug distribution system and to explore the effects of combinations of interventions. In addition, other aspects of each drug distribution system could be investigated. For example, some of the options investigated in the present study have important implications for pharmacy workload. The model developed in the present study can be used to predict the numbers of medication orders that would require dispensing each evening if pharmacy opening hours were increased or if the residency service was extended. It has previously been found that the introduction of computerised prescribing can have a dramatic effect on dispensary workload (Farrar *et al*, 1998); this could also be studied using a more comprehensive model.

In summary, the construction of a simulation model of the hospital drug distribution system was found to be a potentially useful way of exploring the effects of different changes to the system. The model was used to identify five changes to the system that were predicted to reduce U-MAEs by a clinically meaningful amount on each study ward; a sensitivity analysis suggests that these conclusions are robust. However in order to explore the validity of the model's predictions, it was decided to compare the U-MAE rates predicted by the model with those obtained in practice. This aspect of the present study will be addressed in Section D of this thesis, which describes the trial of a new drug distribution system on the two study wards. However, before this trial could take place, a method for assessing MAE severity was also required. This will be considered in the next section.

Part C

Assessing the Severity of Medication Administration Errors

‘When you can measure what you are speaking about, and express it in numbers, you know something about it; but when you cannot measure it ... your knowledge is of a meagre and unsatisfactory kind.’

Lord Kelvin (1889)

Popular lectures and addresses vol 1:

Electrical units of measurement.

Chapter Seven: Introduction and literature review

7.1 Introduction

The medication administration error (MAE) rate has often been used to assess and compare different drug distribution systems (Barker, 1969; Hynniman *et al*, 1970; Miller, 1977; Allan and Barker, 1990; Dean *et al*, 1995). However, few studies have considered the severity of the errors that occur. MAEs range from those with very serious consequences to those that have little or no impact on the patient; measuring only their incidence overlooks such differences (Uzych, 1996). It is possible that changing the drug distribution system could affect the severity of MAEs without affecting their frequency. It was therefore considered essential to assess the severity as well as the incidence of the MAEs identified in the proposed trial of a new drug distribution system. In this context, the *severity* of an MAE was considered to reflect the risks to the patient involved.

This part of the thesis considers in detail the assessment of MAE severity, beginning in this chapter with a critical appraisal of existing methods. Chapter Eight then describes the development and validation of a new method.

7.2 Objectives

1. To review existing methods for assessing MAE severity.
2. To decide if any of the existing methods were suitable for use in the present study.

7.3 Literature Review

Literature relating to the assessment of MAE severity was identified using the Medline (1966 to September 1998), Embase (1985 to September 1998), CINAHL (1982 to June 1997) and HealthSTAR (1975 to December 1997) databases. 'Medication error' was

used as the search term and the retrieved abstracts used to identify any reports that included an assessment of MAE severity.

Many approaches to the assessment of MAE severity were identified. Some are based on actual patient outcomes, some on the subjective assessment of potential patient outcomes and others on proxy indicators of severity. However, any measurement tool must be valid (be a true measure of MAE severity), reliable (produce the same result for the same MAE regardless of who assesses the error and when) and practical to use. The existing methods were therefore examined in relation to their validity, reliability and practicality for use in the present study, in which it was likely that an observation-based method would be used for data collection.

7.3.1 Methods based on actual patient outcomes

Probably the most obvious method of assessing an error's severity is to consider directly the magnitude of any resulting harm. Since the discovery of an error may be accompanied by appropriate remedial action, the extent of any such intervention can also be considered. For example, Demers and Moore (1988) classified errors as follows:

Level 0: No medication error.

Level 1: Error occurred, no harm to the patient.

Level 2: Error; increased need for monitoring, no change in vital signs.

Level 3: Error; increased monitoring, transient change in vital signs, no harm to patient.

Level 4: Error; increased monitoring, change in vital signs - treatment needed, change in length of stay or effect on an investigational drug protocol¹.

Level 5: Error; increased monitoring and treatment, change in patient morbidity.

Level 6: Death.

(Demers and Moore, 1988:52)

¹

When clinical trials are carried out, any departure from a defined drug administration procedure will usually mean that the patient concerned has to be excluded from the trial.

This severity index was subsequently modified by Hartwig *et al* (1991) and Schneider and Hartwig (1994) and has since been adopted by the US National Coordinating Council for Medication Error Reporting and Prevention (Dunn and Wolfe, 1997).

Many similar scales have been developed, all of which were designed to grade the severity of errors identified in US incident-reporting schemes (table 7.1). However there are wide variations in the categories and definitions used; comparisons between studies using different scales are therefore impossible.

Authors	Categories	Low anchor	High anchor	Assessor(s)
Demers & Moore, 1988	7	No error occurred	Death	QA * co-ordinator, nurse and pharmacist
Brandt <i>et al</i> , 1988	3	Minimal or no intervention required	Potentially life-threatening	Nurse
Raju <i>et al</i> , 1989	4	No apparent injury	Substantial injury	Pharmacy manager
Hartwig <i>et al</i> , 1991	7	No error occurred	Death	Nursing QA * coordinator
Bechtel <i>et al</i> , 1993	6	No effect noted	Critical incident	Nurse specialist
Bradbury <i>et al</i> , 1993	6	No patient harm	Patient death	Not stated
Wolf, 1994	4	No harmful effect	Maximally harmful effect (death)	Not stated

Table 7.1 Medication error assessment methods based on actual patient outcomes.

* QA: quality assurance

The validity of these methods can be considered relatively high as they are based directly on patient outcomes, although a potential problem is that the extent of patient harm may depend on the time delay between an error's occurrence and its discovery. Only Bechtel *et al*'s scale (1993) was assessed in terms of inter-rater reliability; this was reported to be 0.79 but the statistic used was not specified. However, the main disadvantage associated

with these methods is that they are impractical for use in observation-based studies. If the prescriber's original order is used for medication administration, an observer will be aware of any errors as they occur and may be ethically obliged to intervene to prevent them from affecting the patient (Ridge *et al*, 1995). Identifying patient outcomes will therefore be impossible. Where the original medication order is not used for administration, errors have to be identified retrospectively and it may be impossible to identify any clinical effects due to the time delay between an error's occurrence and its identification. For example, in an early observation-based study, Barker (1966) made a retrospective review of the medical records of all patients in whose drug therapy an MAE had occurred. He found that the effects of drug therapy were documented in insufficient detail to identify any error-related harm. A similar problem was encountered in a UK study of omitted doses (Pare, 1995). It was therefore considered that outcome-based severity assessment methods were unsuitable for use in the present study.

7.3.2 Methods based on subjective assessment of potential patient outcomes

Subjective assessments have been used in a small number of observation-based studies and rely on one or more experts judging the likely outcomes of the errors identified. For example, in an Australian study, errors were classified as being of low significance, potentially significant or significant (Rippe and Hurley, 1988); the reliability and validity of this classification process were not considered. In a more recent UK study (Nixon and Dhillon, 1996), a doctor, a nurse and a pharmacist were asked to assess the severity of a sample of 25 errors, using categories of 'saves life' (meaning that the observer intervened to prevent an error that would have resulted in death), 'organ damage', 'serious' and 'minor'. There was good agreement between the pharmacist and the doctor ($\kappa = 0.77$), but poor agreement between the nurse and both the doctor and the pharmacist ($\kappa = -0.05$ and 0.13 respectively). Validity was not assessed.

It was considered that although subjective assessment methods are practical for use in observation-based studies, existing methods have not been adequately assessed in terms of validity or reliability.

7.3.3 Methods based on proxy indicators

These methods typically consider objective measures such as the type of error or the type of drug involved, and attempt to relate these to MAE severity. For example, one of the first MAE studies used as an indicator of severity the therapeutic classification of the drugs involved (Barker *et al*, 1966); the same approach was subsequently adopted by Hynniman *et al* (1970) and Tisdale (1986). In these studies, therapeutic classifications of the American Hospital Formulary Service were reviewed to identify those containing drugs that were likely to be associated with serious effects if given incorrectly. Drugs in the 'serious' category included those affecting the central nervous system, antibiotics and cardiovascular drugs. Drugs in the 'not serious' category included gastrointestinal drugs, vitamins and vaccines. The validity of this method is limited by the many exceptions to the broad therapeutic classifications. For example, an error involving the intravenous administration of a vaccine intended for intramuscular use (which would fall into the 'not serious' category) may have more serious consequences than the administration of a nifedipine capsule instead of a nifedipine slow release tablet (which would fall into the 'serious' category). Schnell (1976) instead used the type of MAE (omission, wrong dose and so on) as an index of severity.

Other instruments contain multiple items, the scores for which are summed to give an overall index of severity (table 7.2). These were all developed in the USA to standardise the level of disciplinary action taken against nurses involved in medication errors.

The reliability and validity of these instruments have rarely been considered. The El Dorado Medication Error Tool (EDMET) is the only one that has been evaluated in terms of both reliability and validity (Cobb, 1986a). In this case, six nursing supervisors twice assessed twelve MAEs; correlation coefficients of 0.91 and 0.95 were reported for inter-rater and test-retest reliability respectively. However, the type of correlation coefficient was not specified. In an attempt to investigate validity, EDMET scores were compared with the nursing supervisors' subjective scores on a 1 to 10 scale. A correlation coefficient of 0.79 was obtained and the author suggests that the scale has relatively high

validity. However, a recent observation-based MAE study suggests otherwise (Ogden, 1996). In this study, 131 MAEs were scored using both the EDMET and Demers and Moores' (1988) severity index (section 7.3.1). Overall correlation between the two was low (Spearman's rank correlation coefficient = 0.29), and the validity of the EDMET disputed. Each scale did, however, have to be adapted for use in an observation-based study, and the extent to which this may have affected their validity was not discussed. A possible explanation for any lack of correlation between the two scales is that they were developed for very different purposes. The EDMET was designed to determine the disciplinary action appropriate for the nurse responsible for an error, while Demers and Moores' index was designed to classify actual patient outcomes.

Authors	Item					
	Type of drug	Type of MAE	Route of admin.	Time before reported	Intervention required	Patient's condition
Barker, 1966	✓					
Schnell, 1975		✓				
Rasic <i>et al</i> , 1989	✓				✓	
Tyndall & Carlson, 1990	✓	✓	✓			✓
Walters <i>et al</i> , 1992		✓		✓	✓	
Mee <i>et al</i> , 1995	✓	✓				
Cobb, 1986a	✓	✓	✓	✓		

Table 7.2 Proxy indicators of severity used in existing instruments.

Walters *et al* (1992) assessed inter-rater reliability for their scoring instrument; a correlation coefficient of was 0.91 reported. However, this figure represents the agreement between two groups of nurses that each generated a consensus score, whereas the instrument was intended for use by single nursing supervisors. Again, the correlation

coefficient used was not specified.

These instruments are relatively quick and simple to use, and their objectivity means that reliability is likely to be high. However, validity is a serious concern and none of the existing methods were considered suitable for use in the present study.

7.4 Discussion

For the present study, a method based on either proxy indicators or the subjective assessment of potential outcomes was required; a method based on actual patient outcomes was inappropriate. However, there are two major limitations associated with existing methods. First, no existing method has been adequately assessed in terms of reliability and validity. Second, all were designed to score the severity of each MAE, such as the omission of one dose, individually. This may not adequately reflect the severity of errors that occur repeatedly. For example, an individual omission error may be of low significance, but if the same error occurred in ten consecutive doses administered to the same patient then this may be of more concern. With the scales previously developed, each of these doses would be considered individually, while assessing the whole series may better reflect the total risk to the patient.

It was concluded that a new method for assessing severity was required for use in the present study, one that was reliable, valid and practical, and could be used to assess single and repeated MAEs. The next chapter describes its development.

Chapter Eight: The development of a reliable and valid method for assessing the severity of medication administration errors

8.1 Introduction

This chapter describes the development of a new method for assessing medication administration error (MAE) severity, one that is valid, reliable and does not require knowledge of actual patient outcomes. In the previous chapter, it was concluded that two approaches could be investigated: subjective assessment of potential patient outcomes or objective assessment using proxy indicators of severity. An assessment method based on each approach was developed, but the validity of the objective method was lower than desired (Appendix 10). This chapter describes the development of the subjective method.

All subjective assessments are, by definition, influenced by judges' feelings, knowledge and opinions; agreement amongst individuals may therefore be low. For example, it has been suggested that health care professionals of different disciplines (Williams and Talley, 1994; Nixon and Dhillon, 1996) and nurses of different grades (Wolf *et al*, 1996b) disagree in their assessment of MAE severity. As a result, subjective MAE severity assessments made by one judge would be expected to have low reliability. A potential way of increasing reliability is to ask a number of judges to carry out the assessments and then calculate their mean scores; reliability would be expected to increase with the number of judges (Streiner and Norman, 1995). However, the number of judges required to give an acceptable level of reliability is not known and the importance of their professional groups has not been explored. Furthermore, the validity of subjective MAE assessment has never been considered. The work described in this chapter attempts to address these issues, with the aim of developing a reliable and valid method for assessing MAE severity.

8.2 Objectives

1. To select an appropriate scale with which to measure MAE severity.
2. To determine the minimum number of judges required to produce reliable mean MAE severity scores.
3. To determine whether the judges' professions affect the scores obtained.
4. To assess the validity of the judges' scores.

8.3 Methodology

Three methodological issues had to be considered. These were how the judges were to give their responses, how to address reliability and how to measure validity. Each of these will be addressed in turn.

8.3.1 Scaling responses

Various methods were considered and tested during pilot work. A continuous scale, numbered from zero to ten (figure 8.1), was subsequently selected; this gave higher inter-rater reliability and took less time to complete than the other scales tested. Eleven points were used so as to maximise discriminatory power and minimise the problem of end-aversion bias (Streiner and Norman, 1995). The anchors were chosen to give as wide a range of responses as possible and thus maximise the sensitivity of the scale. Initially, the low anchor had been phrased as 'no clinical effects on the patient', but pilot work suggested that increased pain or discomfort could be interpreted as 'no clinical effects', and thus rated as zero. 'No effects' was therefore used instead.

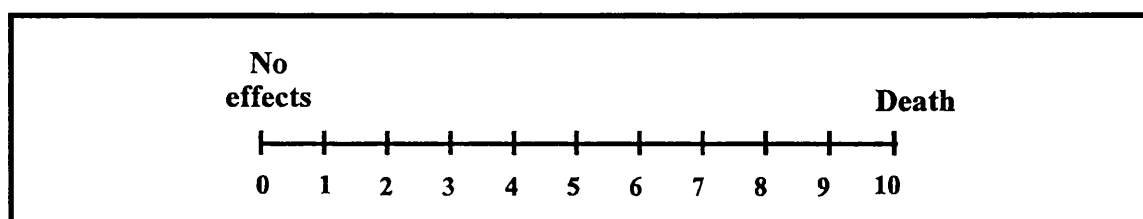


Figure 8.1 The scale on which judges indicated the potential clinical significance of each MAE.

8.3.2 Reliability

According to classical reliability theory, several different types of reliability are considered to exist; these include test-retest and inter-rater reliability (Bowling, 1997). However such measures of reliability are usually applied retrospectively to the results of an assessment; if the level of reliability is deemed to be inadequate, there is no structured way to determine how best to increase it. An alternative approach is to use generalisability theory (Cronbach *et al*, 1972; Shavelson *et al*, 1989). This method has been used to design assessment methods in a number of health care settings; these include the assessment of postgraduate pharmacists' course work (Smith *et al*, 1995), the quality of community pharmacists' advice (Smith *et al*, 1990) and patients' functional status (Evans *et al*, 1981). Generalisability theory is based on the premise that within any assessment procedure, variance in scores can be attributed to different identifiable sources. Once the variance attributable to each of these sources has been quantified, the most efficient way of reducing unwanted variance can be determined. Generalisability theory therefore has several advantages over classical reliability theory (Shavelson *et al*, 1989; Streiner and Norman, 1995). First, all the sources of variance are explored at the same time, allowing interactions amongst them to be identified. Second, the subject variance is a single estimate based on all the available data and is thus relatively precise. Finally, strategies to optimise the reliability of a test can be identified. It was therefore decided to ask a number of judges to twice assess the severity of a series of MAE cases, and then use generalisability theory to investigate how the number of judges, their professional discipline and the number of testing occasions would affect the reliability of the mean scores obtained.

8.3.3 Validity

A standard approach to the assessment of validity is to consider criterion validity; this involves comparing the measure of interest with another measure that is generally accepted to be valid (Bowling, 1997). However, there is no accepted method for assessing MAE severity and there was thus no obvious criterion measure with which to

compare the judges' scores. Since the aim of the scoring process was to indicate the risks to the patient involved, it was decided to use the outcomes of reported MAEs with which to assess validity. Some MAEs with known outcomes were therefore included amongst the cases that the judges were asked to assess. The premise was that if the scoring method is valid, the scores given to the cases with known outcomes should reflect the relative severity of those outcomes.

8.4 Methods

8.4.1 Recruitment of judges

It was decided to recruit ten doctors, ten pharmacists and ten nurses from a range of different hospitals. The chief pharmacist, the director of nursing and the director of medicine were therefore contacted in four NHS trusts in the South Thames area, to request permission to recruit volunteers from amongst their staff. At the time of the study, the trusts contacted represented two teaching sites (St. George's Healthcare NHS Trust, and Guy's and St. Thomas' NHS Trust) and two non-teaching sites (Brighton Health Care NHS Trust and Lewisham NHS Trust). In each department where permission was granted, a letter was sent to all pharmacists (grade D and above), all general physicians and general surgeons (senior house officers and above), and all nurses on the general medical and general surgical wards (grade E and above). This letter (Appendix 11) explained why an MAE assessment method was being developed, asked for volunteers to take part in the study and specified that a £10 gift voucher would be given to each participant.

Respondents were grouped by profession, grade and hospital, and a stratified random sample of thirty respondents (ten doctors, ten nurses and ten pharmacists) was selected. The volunteers who were not selected were sent a letter informing them accordingly.

8.4.2 Scoring

The thirty health care professionals selected were sent brief descriptions of fifty MAE cases (Appendix 12). Some of these cases referred to single errors, others to repeated MAEs occurring in the same patient. The volunteers were instructed to score the cases in terms of their 'potential clinical significance' using the scale illustrated in section 8.3.1. Appendix 13 shows the instructions sent to each health care professional.

The fifty cases were selected from a range of sources, so that approximately equal numbers were, in the researcher's opinion, 'minor' (very unlikely to have any adverse effects on the patient), 'moderate' (likely to cause some adverse effects to the patient or interfere with therapeutic goals, but very unlikely to result in death or lasting impairment), and 'severe' (could cause death or lasting impairment). This was so that validity and reliability could be assessed for the whole range of cases likely to be encountered and so that the distribution of scores obtained would not be highly skewed. Five cases reported in the literature to have resulted in 'minor' outcomes (no adverse effects), five with 'moderate' outcomes (some adverse effects but no lasting impairment) and six with 'severe' outcomes (death or lasting impairment) were included so that the validity of the scoring process could be assessed.

Judges were asked to record the time taken to score all fifty cases, and to add any relevant comments regarding the scoring procedure. The response sheets included a reference number so that non-responders could be identified. About two weeks after the receipt of the completed scores, each respondent was sent ten of the cases to score again, together with a gift voucher. It had been intended to ask the judges to repeat the assessment of all fifty cases, but pilot work indicated that this was considered too time-consuming and likely to result in a low response rate.

8.4.3 Analysis

Analysis using generalisability theory takes place in two stages. First, the major sources

of variability in the assessment process are determined using an analysis of variance. This is referred to as a G (generalisability) study and involves calculation of the generalisability coefficient, which is a measure of reliability. Second, the effects on the generalisability coefficient of different modifications to the assessment procedure are investigated; these are called D (decision) studies.

8.4.3.1 G studies

The potential sources of variability in the assessment of MAE severity were considered to be the inherent differences amongst the cases themselves (CASE), the occasion on which they are rated (OCCASION), the judge (JUDGE), the judge's professional discipline (PROFESSION), and the interactions amongst them. Because each judge can be a member of only one profession, the factor JUDGE is considered to be nested within the factor PROFESSION. Since scores were obtained on more than one occasion for only ten of the cases, there were two ways in which a G study could be carried out, depending on the data set used:

Model 1 OCCASION x CASE x JUDGE (using the 10 cases tested twice)

Model 2 CASE x JUDGE:PROFESSION* (using all 50 cases)

* the colon indicates nesting

Model 1 ignores the effect of the different professions, while model 2 ignores the effect of the occasion on which the case was assessed. A model that would take into account all sources of variance for the ten cases with repeated scores, OCCASION x CASE x JUDGE:PROFESSION, could not be used as the variable-to-case ratio was too high to carry out an analysis of variance.

The data were therefore analysed using both models 1 and 2 to determine the contributions of each factor to the variance in scores. Repeated measures analyses of variance were first carried out, using the Statistics Package for the Social Sciences (version 7.5.1, SPSS Inc, Chicago). The resulting values for the mean squares were then used to calculate the variance attributable to each source, using equations for the expected

mean squares based on those described by Streiner and Norman (1995: 132), and Cronbach *et al* (1972). Where estimated variance components were computed to be negative, a value of zero was assumed (Shavelson *et al*, 1989).

An overall generalisability coefficient and coefficients equivalent to inter-rater reliability and test-retest reliability were then calculated (Streiner and Norman, 1995: 135).

8.4.3.2 D studies

Generalisability coefficients for different numbers of judges and different numbers of testing occasions were calculated using the formulae given by Streiner and Norman (1995: 136) (after correcting their typographical errors). A generalisability coefficient of 0.8 or above was considered to represent an acceptable level of reliability (Smith *et al*, 1995).

8.4.3.3 Validity

The mean score for each case with a known outcome was calculated and compared with the outcome reported.

8.5 Results

8.5.1 Recruitment of judges

Of the four NHS trusts approached, all four chief pharmacists, three of the four directors of medicine and two of the four directors of nursing gave permission for their staff to be contacted. A third director of nursing did not want her staff to be contacted directly, but gave the name of one nurse who was interested in taking part. The director of medicine who did not want his staff to participate considered that doctors were too busy to take part without substantial financial reimbursement. The fourth director of nursing did not reply to the researcher's letters.

It was decided to write to pharmacists in only three of the four hospitals, as it was

anticipated that there would be a high response rate amongst pharmacy staff. Table 8.1 summarises the health care professionals initially contacted, the response rates and the staff who were selected to take part in the study. Initial response rates differed amongst the disciplines; these were 88% for the pharmacists, 60% for the nurses and 37% for the doctors. The grades of the medical staff non-respondents were compared with those of the respondents and no significant difference identified ($p = 0.10$; chi square test).

NHS Trust	Professional group	Letters sent	Responses	Response rate	Number selected
St George's	Pharmacists	21	18	86%	4
Lewisham	Pharmacists	8	8	100%	2
Brighton	Pharmacists	20	17	85%	4
St George's	Nurses	49	28	57%	5
Lewisham	Nurses	1*	1	100%	1
Guy's/St Thomas'	Nurses	12	8	67%	4
St George's	Doctors	26	10	38%	5
Lewisham	Doctors	15	3	20%	2
Brighton	Doctors	13	7	54%	3
TOTAL		165	100	61%	30

Table 8.1 Summary of the health care professionals initially contacted, the response rates and the sample selected to take part in the study.

* The director of nursing for this trust gave the researcher the name of one nurse who was interested in taking part.

Table 8.2 shows the demographic details of the thirty judges selected.

Reference number	Trust	Discipline	Grade*	Speciality
SGH01	St George's	Pharmacist	D	Not stated
SGH02	St George's	Pharmacist	E	Not stated
SGH03	St George's	Pharmacist	D	Not stated
SGH04	St George's	Pharmacist	D	Not stated
SGH05	St George's	Nurse	F	Medicine
SGH06	St George's	Nurse	F	Surgery
SGH07	St George's	Nurse	E	Surgery
SGH08	St George's	Nurse	F	Surgery
SGH09	St George's	Nurse	F	Medicine
SGH10	St George's	Nurse	G	Medicine
SGH11	St George's	Doctor	SHO	Surgery
SGH12	St George's	Doctor	SHO	Surgery
SGH13	St George's	Doctor	SHO	Medicine
SGH14	St George's	Doctor	SHO	Surgery
SGH15	St George's	Doctor	Senior	Medicine
L1	Lewisham	Pharmacist	D	Not stated
L2	Lewisham	Pharmacist	D	Not stated
L3	Lewisham	Nurse	Not stated	Pain control
L4	Lewisham	Doctor	Consultant	Medicine
L5	Lewisham	Doctor	Consultant	Medicine
B1	Brighton	Pharmacist	Not stated	Not stated
B2	Brighton	Pharmacist	Not stated	Not stated
B3	Brighton	Pharmacist	Not stated	Not stated
B4	Brighton	Pharmacist	Not stated	Not stated
B5	Brighton	Doctor	SHO	Surgery
B6	Brighton	Doctor	Consultant	Medicine
B7	Brighton	Doctor	SHO	Surgery
T1	Guy's/St Thomas'	Nurse	F	Surgery
T2	Guy's/St Thomas'	Nurse	F	Medicine
T3	Guy's/St Thomas'	Nurse	F	Medicine

Table 8.2 Demographic details of the thirty health care professionals recruited.

* SHO = Senior House Officer

8.5.2 Scoring

Completed data collection forms were initially received from nine of the ten selected pharmacists, nine of the ten nurses and six of the ten doctors. The non-responders were all from the same hospital. Following the researcher's telephone calls, it transpired that the pharmacist non-responder was studying for an examination and was not able to complete the scoring. The nurse non-responder and one of the doctors had each begun one month's leave. For each of these three, another staff member of the same grade and hospital was randomly selected and used as a replacement. The remaining three doctors completed the scoring following the researcher's telephone call.

Completed scoring sheets were therefore obtained from thirty health care professionals (ten nurses, ten pharmacists and ten doctors). The median reported time required to score all fifty cases was 27.5 minutes (range 12 to 75). Three judges did not record the time taken. The mean scores for each MAE ranged from 0.9 to 9.6 (Appendix 12). Twenty-eight of the thirty health care professionals returned the second set of scores; the two non-responders were doctors at the same teaching hospital.

Eleven of the thirty judges made additional written comments regarding the scoring process; these generally related to difficulties in grading the cases.

"In some circumstances the answers were very difficult in the absence of more clinical data" (L5)

"...it's hard to do initially because you don't know how much more or less serious the examples will get" (SGH02)

"I have recorded/rated effects in terms of severity/danger to the patient. This does not imply that the ones I have scored low are insignificant/excusable/not problematic" (SGH13)

Some of the health care professionals did not give a score to every case. Details of the cases that were not scored are given in table 8.3. Since five of the health care professionals did not give a score to case number 27 (a case in which co-careldopa was administered instead of co-beneldopa), it was decided to omit this case from further analysis. The remaining missing values (representing less than 1% of the total number of data points) were ignored when calculating the mean score for each case. However, to

carry out the analysis of variance, replacement values were calculated using the method described by Armitage and Berry (1994: 277).

Discipline	Trust	Case numbers *
Nurse	Guy's/St Thomas'	6
Doctor	St George's	20
Doctor	Lewisham	3,15,27,30,33,37
Nurse	St George's	12, 27
Pharmacist	St George's	15,21,27
Doctor	Lewisham	11,15,27
Nurse	St George's	3,8
Doctor	St George's	27

Table 8.3 Details of cases that were not scored by all thirty health care professionals.

* Case numbers refer to those given in Appendix 12.

8.5.3 Analysis

8.5.3.1 *G studies*

The analysis of variance table obtained using model 1 (OCCASION x CASE x JUDGE) is shown in table 8.4. Only nine judges could be included; if more judges were included the case:judge ratio was too low to carry out an analysis of variance. Three nurses, three pharmacists and three doctors were therefore randomly selected for inclusion in the analysis. Table 8.5 shows the variance components calculated.

It can be seen that most of the variance can be attributed to differences amongst the MAE cases. Little variance can be attributed to the occasion on which the assessment is made but some to the different judges and the interaction between judges and cases. The residual variance (case x occasion x judge) is relatively large in comparison to the other sources of variance, indicating that there remains some variance unaccounted for.

Source of variance	Degrees of freedom	Mean square	Expected mean square *
Case	9	93.41	$\sigma^2_{c \times o \times j} + 2\sigma^2_{c \times j} + 9\sigma^2_{c \times o} + 18\sigma^2_c$
Occasion	1	0.08	$\sigma^2_{c \times o \times j} + 9\sigma^2_{c \times o} + 10\sigma^2_{o \times j} + 90\sigma^2_o$
Occasion x case	9	2.64	$\sigma^2_{c \times o \times j} + 9\sigma^2_{c \times o}$
Judge	8	39.64	$\sigma^2_{c \times o \times j} + 2\sigma^2_{c \times j} + 10\sigma^2_{o \times j} + 20\sigma^2_j$
Judge x case	72	5.21	$\sigma^2_{c \times o \times j} + 2\sigma^2_{c \times j}$
Occasion x judge	8	3.47	$\sigma^2_{c \times o \times j} + 10\sigma^2_{o \times j}$
Case x occasion x judge	72	1.76	$\sigma^2_{c \times o \times j}$

Table 8.4 Analysis of variance table for model 1: OCCASION(o) x CASE(c) x JUDGE(j).

* σ^2 represents variance.

Source	Variance
Case	4.852
Occasion	0
Occasion x case	0.097
Judge	1.636
Judge x case	1.725
Occasion x judge	0.171
Case x occasion x judge	1.760

Table 8.5 Sources of variance for model 1: OCCASION x CASE x JUDGE.

The overall generalisability coefficient was calculated to be 0.58. This indicates that there is 58% agreement on MAE severity between any two assessments, irrespective of the judge and the occasion on which the case was assessed. The coefficients equivalent to inter-rater and test-retest reliability were 0.59 and 0.78 respectively.

The analysis of variance table for the model CASE x JUDGE:DISCIPLINE is shown in table 8.6. The resulting variance components are summarised in table 8.7.

Analysis of variance results as if crossed				Analysis as actually nested		
Source of variance	Sum of Squares	Degrees of freedom	Source as confounded	Combined sums of squares	Combined degrees of freedom	Mean square Expected mean square *
profession	509.88	2	profession	509.88	2	254.94 $\sigma^2_{jp \times c} + 49\sigma^2_{jp} + 10\sigma^2_{p \times c} + 490 \sigma^2_p$
<u>Within profession</u>						
judge	490.77	9	judge:	1378.49	27	51.06 $\sigma^2_{jp \times c} + 49\sigma^2_{jp}$
judge x profession	887.72	18	profession			
case	8429.82	48	case	8429.82	48	$\sigma^2_{jp \times c} + 10\sigma^2_{p \times c} + 30 \sigma^2_c$
case x profession	509.14	96	case x profession	509.14	96	$\sigma^2_{jp \times c} + 10\sigma^2_{p \times c}$
<u>Within case x profession</u>						
case x judge	1102.19	432	judge: profession x case	3508.64	1296	$\sigma^2_{jp \times c}$
case x judge x profession	2406.45	864				

Table 8.6 Analysis of variance table for model 2: CASE (c) x JUDGE (j):PROFESSION (p).

• σ^2 represents variance.

Source	Variance
Case	5.68
Profession	0.41
Judge:profession	0.99
Case x profession	0.26
Case x judge:profession	2.71

**Table 8.7 Sources of variance for model 2:
CASE x JUDGE:PROFESSION.**

These results suggest that more variance can be attributed to the individual judges than to differences in their profession. Using this model, the generalisability coefficient was calculated to be 0.66 and the coefficient equivalent to inter-rater reliability was 0.67.

8.5.3.2 D studies

The generalisability coefficient was calculated for different numbers of judges and different numbers of occasions using model 1 (OCCASION x CASE x JUDGE). The results are summarised in table 8.8, and indicate that to achieve a generalisability coefficient above 0.8, at least 4 judges must score the cases, each on one occasion.

Increasing the number of occasions on which the cases are scored has very little impact on the generalisability coefficient.

Number of judges	Number of occasions	Generalisability coefficient
1	1	0.575
1	2	0.579
1	30	0.582
2	1	0.725
3	1	0.794
4	1	0.834
5	1	0.859
30	1	0.958

Table 8.8 Generalisability coefficients for different numbers of judges and different numbers of testing occasions.

A D study carried out using the results obtained from model 2 (CASE x JUDGE:PROFESSION) confirmed that the use of four judges should give a generalisability coefficient above 0.8. Using judges from more than one profession has little impact on the generalisability coefficient.

8.5.3.3 Validity

When the mean scores for the sixteen medication errors with known outcomes were examined, there was a clear relationship between the actual patient outcomes and the judges' scores (figure 8.2). A similar picture is obtained if the mean score is calculated using only four judges, however if this graph is plotted using only one judge the three categories show greater overlap.

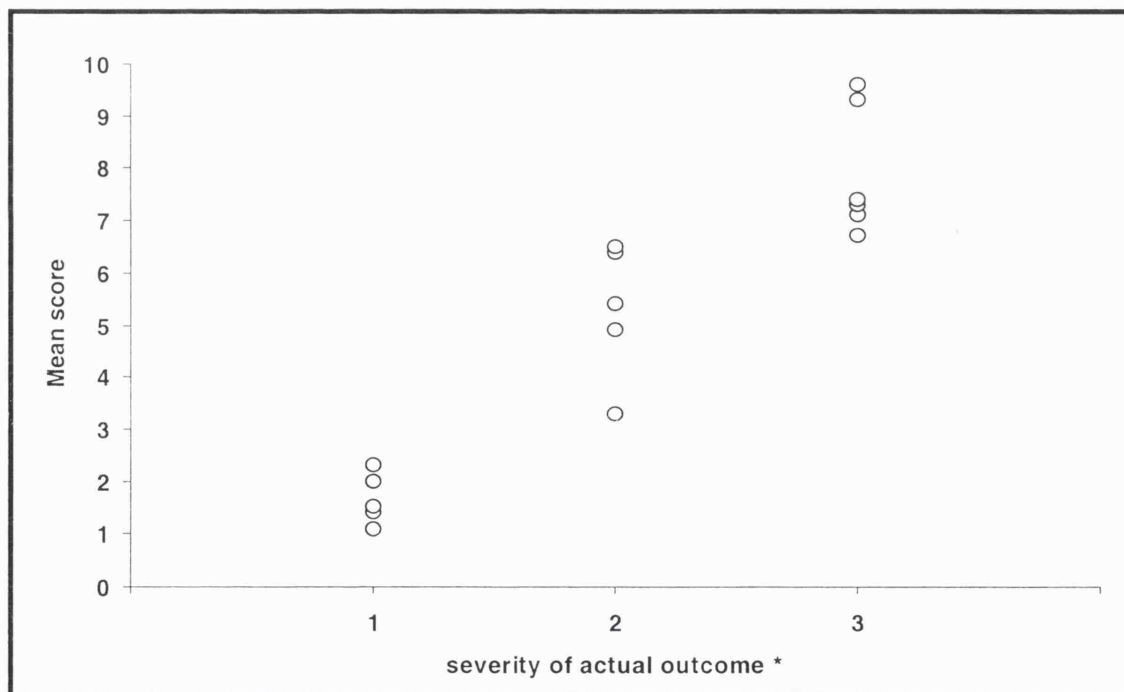


Figure 8.2 Comparison of the judges' mean scores with the severity of the actual outcomes.

* 1 = minor, 2 = moderate, 3 = severe (as defined in section 8.4.2).

Figure 8.2 also suggests that an error given a score of less than 3.0 would be likely to result in an outcome of minor severity, between 3.0 and 7.0 an outcome of moderate severity and above 7.0 a severe outcome.

8.6 Discussion

These results suggest that if any four judges are selected from the population of experienced UK pharmacists, medical staff and nursing staff, their mean scores should be generalisable to those obtained using any other four judges selected from the same population. The results also suggest that such a method is valid, as the scores given to the medication errors with known outcomes reflected the severity of those outcomes.

It was somewhat surprising to find that the professional discipline of the judge contributed less to score variability than did differences amongst individual judges. Previous studies have concluded that judges of different disciplines differ in their assessment of medication errors (Williams and Talley, 1994; Nixon and Dhillon, 1996). However, in each of these studies there was only one representative of each professional group and it is therefore impossible to determine whether differences in scores can be attributed to individual or professional differences. Few other studies have compared assessments given by different professions, although one UK study has shown reasonable agreement between clinicians and pharmacists in the assessment of pharmacists' interventions (Eadon, 1992). The results of the present study suggest that in the assessment of MAEs, judges could in theory be chosen from any one of the three professions. However, selection of at least one judge from each of the three professional groups would facilitate ownership of the results by all health care professionals involved and encourage collaborative efforts to reduce MAEs; it is therefore suggested that at least one pharmacist, at least one nurse and at least one doctor are involved.

There were a number of minor limitations associated with the methods used. First, a linear scale was used to record the judges' responses; this was chosen as these types of scale are simple to use and familiar to most health care professionals. However, any measure of risk should take into account both the probability and the extent of harm (The Royal Society, 1992). Theoretically, medication error severity should therefore be represented using a graph with extent of patient harm along the x axis and the probability of that degree of harm represented by the y axis. Different medication errors would have

different areas under the curve. A simplification of this approach has been used in the assessment of prescribing errors (Hawkey *et al*, 1990), where a judge was asked to estimate the probability of different levels of patient harm occurring. However, the use of such probability distributions is complex; in this study it was decided to simplify the concept of MAE severity by using a single score.

Second, the validity of any MAE assessment method is difficult to assess, as there is no widely accepted instrument with which to compare other methods. In the present study, a series of medication errors with known outcomes was used with which to assess validity. The main limitation associated with this approach is that outcomes reported in the literature may not reflect the likely outcomes in the patient group as a whole. Errors resulting in more severe outcomes may be more likely to be reported in the literature, resulting in some bias. However, this was considered to be the only practical approach.

Third, the scale used does not consider the costs resulting from medication errors. Pilot work suggested that health care professionals considered the financial consequences of medication errors to be directly related to their clinical consequences, and it was therefore decided to focus on the latter. However, a study that compared the costs of medication errors and adverse drug reactions with the severity of their clinical outcomes found no direct relationship (Schneider *et al*, 1995). Scores obtained using the present method may therefore not reflect the financial consequences of MAEs.

Finally, the severity assessment method was developed using the contributions of doctors, pharmacists and nurses. However, the patient's perspective was not included. No previous work has considered patients' views on medication errors; it is not known whether patients are concerned only with the outcome of any errors that occur, or whether the occurrence of an error is perceived to be a problem *per se*. More work is needed to address these issues.

It was concluded that four experienced health care professionals should be asked to assess the severity of each MAE using a scale numbered from zero to ten. The four health care professionals should ideally include a doctor, a nurse and a pharmacist. The mean score

for each MAE can then be used as an index of severity; these scores should be both valid and reliable.

Chapter Ten will describe the use of this method to assess MAEs identified during a trial of a new drug distribution system. First, however, the next chapter will address the trial's methodology.

Part D

Trial of a new drug distribution system

‘To mistrust science and deny the validity of the scientific method is to resign your job as a human. You’d better go look for work as a plant or wild animal’.

PJ O’Rourke (1991)

Parliament of whores.

Chapter Nine: Methodology

9.1 Introduction

Part B of this thesis described the construction of a simulation model of the hospital drug distribution system, and how it was used to predict the effects on unavailability-related medication administration errors (U-MAEs) of different changes to the system. To explore the model's predictive validity, it was decided to measure the U-MAE rates associated with the traditional ward pharmacy system and a new drug distribution system on the two study wards, and then compare these U-MAE rates with those predicted by the model.

To evaluate the full impact of the new drug distribution system on MAEs, it was also necessary to measure other types of medication administration error (O-MAEs) and to assess the severity of the errors identified using the new method developed.

This part of the thesis describes the trial of a new drug distribution system on the two study wards. As highlighted at the beginning of this thesis, there are a number of problems associated with existing MAE research; these include the experimental designs adopted and the imprecise methods and definitions used. These issues were therefore given careful consideration in the present study and will be discussed in detail in this chapter. Chapter Ten then describes the specific methods used to conduct the trial and gives the results obtained.

9.2 Objectives

1. To choose appropriate methods with which to measure U-MAE and O-MAE rates on the two study wards.
2. To develop an appropriate system for the definition and classification of MAEs.

3. To select a suitable experimental design with which to conduct the trial.

9.3 Methods for identifying medication administration errors

Examination of the existing literature reveals many methods that have been used to identify MAEs. These can be classified into three broad areas: observation, self-reporting and examination of physical evidence. In this section, the advantages and disadvantages of each approach will be discussed in relation to the present study, in which it was considered important to determine the incidence of both U-MAEs and O-MAEs as accurately as possible.

9.3.1 Observation

Observation-based methods involve a researcher observing nurses preparing and administering medication, recording details of all doses administered, then comparing these observations with the original medication orders in order to identify any discrepancies. Several studies have compared the numbers of errors detected using observation with the numbers detected using other methods; each found that observation revealed far greater numbers (Barker and McConnell, 1962; Hall *et al*, 1985; Shannon and De Muth, 1987). Observation of medication administration is therefore generally accepted to be the best method for identifying MAEs; in a comprehensive review of medication error research, only studies using this method were considered to be valid (Allan and Barker, 1990). Another advantage of observation is that it allows some of the factors contributing to MAEs to be identified (Barker, 1980). However, observation has two major disadvantages. First, it is possible that the presence of an observer could affect nurses' behaviour and thus the observed MAE rate. Second, observation is very labour-intensive and large sample sizes difficult to achieve. Other methods were therefore given consideration for use in the present study.

9.3.2 Self-reporting

Self-reporting methods include anonymous reports and questionnaires as well as official incident reports that usually require names of the personnel involved. The main advantage of these methods is that they are less labour-intensive than the others described. In the USA, medication error reporting schemes are required to gain hospital accreditation; self-report data are therefore readily available in most hospitals. Numerous analyses of reported errors have been published, many of which claim to have identified relationships between MAE rates and nursing, patient or environmental characteristics (Raz and Kraus, 1989; West *et al.*, 1994; Calliari, 1995; Roseman and Booker, 1995). However, self-reporting relies on someone being both aware of an error's occurrence and willing to report it. Evidence suggests that no-one is aware of the majority of MAEs that occur, and even where someone is aware of an error's occurrence there are many reasons why it may not be reported. These include lack of time, fear of disciplinary action, belief that only serious errors should be reported and uncertainty over what constitutes an error (Barker and McConnell, 1962; Walters, 1992; Gladstone, 1995; Baker, 1997). It has also been suggested that if an incident is perceived to be no-one's fault then it may not be considered an error, and therefore not reported (Baker, 1997). Other quantitative studies confirm that self-reporting grossly underestimates the numbers of errors that occur (Barker and McConnell, 1962; Hall *et al.*, 1985, McNally and Sunderland, 1998). Since it cannot be assumed that reported errors are representative of all those that occur, conclusions based on self-report data cannot be extrapolated to MAEs in general. Self-reporting was therefore considered an unsuitable method for the present study.

9.3.3 Examination of physical evidence

Physical evidence includes the dose units on the ward, the presence of drugs in patients' urine and patients' administration records. Each of these will be considered in turn.

9.3.3.1 Dose unit counts

This method involves counting the doses present on the ward at two different points in

time, recording the number supplied and the number known to have been destroyed during the interim period, and then calculating the amount of each product used. These figures are then compared with the doses that should have been administered according to the prescribers' medication orders, and any discrepancies identified. Some have used this method to identify only omission errors (Goldstein *et al*, 1982); others have also attempted to draw conclusions about other types of MAE (Corak and Hartigan, 1978; Hoffman *et al*, 1984).

This method has several limitations. First, it is impossible to determine the fate of each dose unit. The disposal of a tablet that was accidentally dropped on the floor and the administration of an overdose are indistinguishable, and it is impossible to ascertain which patient receives each dose. This is a particular issue in the ward pharmacy system, where medication is frequently transferred between wards or disposed of at ward level. For example, Ridge *et al* (1996) carried out dose unit counts on six wards in a UK hospital. These authors identified an absolute discrepancy of 40% (expressed as a percentage of the calculated drug usage) after a period of one week, which corresponded to gains of 19% and losses of 21%. These large discrepancies cannot wholly be explained by the occurrence of MAEs because an observational study on the same wards revealed an MAE rate of 3.5% (Ridge *et al*, 1995; Ridge, 1998). Second, counting dose units can be very time-consuming, particularly on wards with large quantities of stock medication. Finally, in a hospital using the ward pharmacy system, the counts would have to take place on the ward. It would therefore be inconvenient for the researcher and the nursing staff if tablet counts were taking place when medication was required for administration, and as with observation, knowledge that the study was taking place could affect the behaviour of the nursing staff involved. For these reasons, counting dose units was considered an unsuitable method for use in the present study.

9.3.3.2 Urinalysis

Urinalysis has been used in a study of MAEs in a psychiatric hospital; patients' urine was tested for the presence or absence of specific drugs and the findings compared with the patients' medication orders (Ballinger *et al*, 1974). The main disadvantage associated

with this method is that inter-patient variation in pharmacokinetic¹ parameters may make the results difficult to interpret. Other disadvantages are that the analyses would be expensive and it would be impractical to test for the presence of every drug that could be administered.

9.3.3.3 Administration records

UK hospital medication administration policies generally state that any doses omitted due to the unavailability of the medication concerned should be documented as such on patients' drug charts. Several researchers have used such records to identify U-MAEs (Pare, 1995; Jenkins *et al*, 1996; Boyle *et al*, 1998). Although this method cannot be used to study O-MAEs, it has the advantages of being less labour-intensive and less intrusive than observation. It can also be carried out covertly, thus avoiding any concerns about the effects of the study on peoples' behaviour. The examination of administration records was therefore considered as a potential method for identifying U-MAEs in the present study. However no studies published to date have assessed the validity of administration records; a pilot study was therefore carried out to compare the data obtained from administration records with those collected using observation.

9.3.4 A pilot study to compare administration records and observation

To investigate the validity of the data obtained from administration records, it was decided to adopt an approach based on the assessment of diagnostic tests. Data obtained using observation were accepted as being correct; the examination of administration records was considered an alternative test to be compared with observation.

A test should detect most cases that have the characteristics of interest (high sensitivity) and exclude most cases that do not (high specificity). In addition, a positive test should usually indicate that a case with the characteristics of interest has occurred (high positive predictive value) (Greenhalgh, 1997). It was considered that the sensitivity, specificity

1

Pharmacokinetics relates to the fate of drugs within the body. Pharmacokinetic parameters summarise the ways in which drugs are absorbed, distributed around the body, metabolised and excreted.

and positive predictive value of medication administration records should all be greater than 90% if the method was to be useful.

9.3.4.1 Objectives

1. To determine the sensitivity, specificity and positive predictive value of administration records for the identification of U-MAEs.
2. To decide whether administration records could be used to identify U-MAEs in the present study.

9.3.4.2 Methods

This pilot study took place on two general medical wards in the study hospital, these were different wards to those on which the trial was to take place. The first had 28 beds and was studied for four consecutive days; on this ward the nursing staff administered all 6 am doses at 8 am and all 2 pm doses at noon. The second had 20 beds and was studied for five consecutive days; on this ward all 8 am doses were administered at 6 am and all 2 pm doses at noon. On each ward, there were therefore four drug administration rounds each day. According to hospital policy at the study site, if a dose is not administered, a cross is recorded in the relevant section of the drug chart and the relevant reason documented on the chart's reverse.

On each ward, all four drug rounds were observed each day and the administration records examined concurrently. A second suitably trained observer carried out half of the data collection. The observers recorded details of all regularly scheduled oral and inhaled doses given or omitted, how each was documented on the drug chart, and in the case of omitted doses, the actual reason for the omission. If a drug was documented as being unavailable, the observer determined if this was actually the case. Intravenous, topical, rectal and controlled drugs were administered separately from the main drug round and were therefore not observed. The administration records' sensitivity, specificity and positive predictive value were calculated according to the following formulae (Greenhalgh, 1997):

$$\text{sensitivity} = \frac{\text{true positives}}{\text{true positives} + \text{false negatives}} \times 100\%$$

$$\text{specificity} = \frac{\text{true negatives}}{\text{true negatives} + \text{false positives}} \times 100\%$$

$$\text{positive predictive value} = \frac{\text{true positives}}{\text{true positives} + \text{false positives}} \times 100\%$$

In this context, a true positive is a genuine U-MAE that is documented as such on the drug chart. A false positive is a dose that is documented as being omitted due to unavailability but is actually available on the ward and therefore not a U-MAE. A true negative is a dose that is not a U-MAE and not documented as such on the drug chart. A false negative is a U-MAE that is not documented accordingly.

In order to identify any effects of the observation itself on documentation practice, a drug chart survey was carried out on the Friday of the week before each study week, the study week itself and the week after each study week. In each case, the researcher counted the number of doses due in the preceding five days for which a cross had been made on the drug chart (indicating that the nurse had not given the dose), and the number of crosses for which a corresponding reason was documented. If the presence of an observer affected documentation practice, it was anticipated that the proportion of crosses for which a reason was documented would increase during the study week.

9.3.4.3 Results

The results are summarised in figure 9.1. Observation revealed that 22 (2.2%) of 1002 doses were omitted due to unavailability of the drugs concerned, while the information documented on the administration records suggested that only 14 (1.4%) were unavailable.

There were 975 true negatives, 13 false negatives, 9 true positives and 5 false positives. The sensitivity of a drug chart audit for identifying doses omitted due to unavailability was 41%; the specificity was 99%. The positive predictive value was 64%. Results of the drug chart surveys are shown in table 9.1. If the data from the unobserved periods are combined, 45% of crosses had a corresponding reason documented, compared with 50% during the observed periods. This difference of 5% is not statistically significant (95% confidence interval for the difference - 27.0% to 17.0%). However the sample size is very small and it is therefore difficult to draw any firm conclusions.

Ward	Unobserved doses before study week	Observed doses during study week	Unobserved doses after study week
1	18/26 [*] (69%)	8/14 (57%)	5/23 (22%)
2	2/6 (33%)	7/16 (44%)	1/3 (33%)
Total	20/32 (63%)	15/30 (50%)	6/26 (23%)

Table 9.1 Results of the drug chart surveys.

^{*} Figures refer to the number of crosses on the drug charts with a corresponding reason documented, divided by the total number of crosses on the drug charts.

9.3.4.4 Discussion

False negatives and false positives were both identified. False negatives occurred where doses were omitted due to unavailability but not documented as such on the drug chart. False positives occurred where nurses mistakenly assumed that medication was unavailable; this typically occurred where the medication concerned could not be found as it was stored at the patient's bedside, kept in the refrigerator or labelled by brand name. There was no obvious effect of the observer on documentation practice. The specificity of the drug chart audit was high, but the sensitivity and positive predictive value were low. It was concluded that U-MAE data obtained only from administration records were too unreliable for use in the present study.

9.3.5 Choice of data collection method for the present study

Given the deficiencies associated with the other methods described, it was concluded that

an observation-based method should be used in the present study. However, having made this decision, there were other methodological issues to be addressed.

9.4 Methodological issues in observation-based studies

As highlighted in section 9.3.1, there are two major problems associated with observation. The first is the potential effect of the research on the behaviour of the individuals observed, the second that it is labour-intensive. A further methodological issue that must be considered in any observation-based MAE study is whether or not the researcher should intervene to prevent errors from occurring. These three points will be considered in turn.

9.4.1 The effect of the research on the individuals observed

A major concern about the validity of observational data concerns the effect of the research on the individuals observed. People may behave differently when they know they are being observed compared with how they behave at other times, a phenomenon sometimes referred to as the Hawthorne effect (Katz and Kahn, 1966). In the case of MAE research, the error rate could increase if the researcher causes distractions or makes nurses nervous. Conversely, if nurses are more careful in the researcher's presence, the MAE rate may be reduced. There are two approaches to tackling this problem. The first is to reduce the effects of the observation as much as possible. The second is to quantify any remaining effect so that its influence on the study's results can be taken into account.

9.4.1.1 Reducing the effects of observation

In many situations covert observation, in which the people being studied are unaware of the observation, is considered more likely to capture what really happens than when people are aware that they are being studied (Patton, 1990). In MAE research, however, the required proximity of the researcher to the nurse administering medication makes covert observation impossible. There has also been considerable debate over the ethics of covert research and it is generally accepted that investigations should be covert only

where there is no alternative (Bok, 1978).

Although covert observation is not a practical option, most observational studies of MAEs have used disguised observational techniques; nurses have been aware of the observation but unaware of its true purpose (Allan and Barker, 1990). For example, nursing staff have been told that the observation is for a work study (Dean *et al*, 1995; Ridge *et al*, 1995; Gethins, 1996) or a study of problems associated with the drug distribution system (Allan and Barker, 1990). However, ethical questions arise with deception as well as with covert research (Bok, 1978) and Ridge *et al* (1995) suggest that the undisguised study of MAEs is both feasible and preferable. It has also been pointed out that studies cannot necessarily be categorised as either disguised or undisguised; instead they can take various positions along a continuum (Patton, 1990).

In the present study, it was decided to give a partial explanation as to the purpose of the observation. Ward staff were informed that the researcher wanted to determine whether medication was available when needed, whether the correct medication could easily be located and whether any other problems occurred during the drug round. However, the word 'error' was avoided due to concerns that this could result in the observation being perceived as a threat.

Other methods of reducing the effects of observation include being unobtrusive, not asking the subject to change his or her normal activities for the convenience of the researcher and avoiding making value-laden statements (Barker, 1980). It is generally accepted that when individuals are observed in a familiar environment and the researcher is unobtrusive and non-judgemental, their behaviour quickly returns to normal (Kerlinger, 1986). This was demonstrated in a previous MAE study, in which some nurses systematically checked patients' name bands and medication expiry dates during the first observed drug round, but never thereafter (Dean, 1993).

Although other observational studies have been carried out using trained observers, Bonal *et al* (1981) recruited patient collaborators who were asked to record details of all doses

administered. This method may be less likely to affect the behaviour of the nurses observed, but it is likely to underestimate the true MAE rate as the administration of an incorrect medication with a similar appearance to the medication intended may not be detected. There may also be ethical problems associated with this approach and it was not considered appropriate for the present study.

9.4.1.2 Estimating the effects of observation

Even where observation is unobtrusive and non-judgemental and all precautions have been taken to reduce its effects, it is still possible that the presence of a researcher may affect nurses' behaviour during the drug round. Several attempts have been made to identify any such effects.

In the USA, Barker *et al* (1966) interviewed 28 of 32 observed nurses, each of whom had been observed for five consecutive working days. Nurses were asked how they were affected by the researcher's presence and whether they remembered behaving differently as a result. A variety of responses were given, but it was concluded that the observation was unlikely to have biased the results. In the same study, Barker *et al* also examined the MAE rates for each observed day for each nurse; they hypothesised that if the presence of the observer affected nurses' practice, this effect was likely to be greatest at the beginning of the observation period. However, no time-related change in the mean error rate was identified.

In the UK, Ridge (1998) calculated the MAE rate for each observed day of his seven-day observation periods and found it to be slightly lower on the first day; this effect was not statistically significant. However, nursing shift patterns mean that days of the study are unlikely to correspond to days of observation for each nurse. Dean (1993) administered questionnaires to observed nurses; only two of the 27 respondents claimed that the presence of an observer significantly affected their work.

In the present study, it was decided to use two different methods to identify any effects of the observation on nurses' practice. The first involved calculation of separate O-MAE

rates for all those rounds that were a nurse's first observed round, all those that were a nurse's second observed round, and so on. It was assumed that if observation had any effect on MAEs, this would be more apparent in the O-MAE rate than in the U-MAE rate. A logistic regression analysis was then used to identify any change in the probability of an O-MAE occurring with repeated observation.

The second method involved identifying an aspect of practice that could be measured during both observed and unobserved periods. As discussed previously, hospital policy at the study site dictates that whenever a dose is not administered, a cross should be recorded in the relevant section of the drug chart and the relevant reason documented on its reverse. However, the pilot study described in section 9.3.4 revealed that where a cross was placed on the drug chart, a corresponding reason was documented in only about 50% of cases. If the presence of an observer affects nurses' practice, it was anticipated that the proportion of omitted doses for which a reason was documented would be higher during observed periods than at other times. It was therefore decided to adopt the same approach used in the pilot study and measure at the end of each observation period the proportion of doses with a cross on the drug chart for which a corresponding reason was documented. These proportions were then compared with those for unobserved periods.

9.4.2 The labour-intensive nature of observation

On each study ward, the first daily drug round started at about 5:30 am; the last finished at about 11 pm. It was considered important that consecutive drug rounds were observed so that the repetition of identical errors could be identified. The observation of consecutive rounds also provides information about the exposure of individual patients to MAEs. It was therefore decided to employ a second trained data collector so that all drug rounds could be observed during each study period, including those during evenings and weekends.

9.4.3 Intervention

In US observation-based studies, the researcher does not have access to the original medication order at the time of administration; he or she is therefore unaware of errors as they occur and unable to prevent them. Indeed, it has been suggested that to avoid liability the researcher should actively avoid gaining familiarity with the original orders before observation (Allan and Barker, 1990). However, in hospitals using the ward pharmacy system it is almost impossible for the researcher to avoid seeing the original medication order at the time of administration. The researcher is therefore aware of errors as they occur and may be faced with an ethical dilemma regarding intervention. It could be argued that because the error would have occurred in the researcher's absence, the researcher has no obligation to intervene. But if the researcher is aware that an error is about to occur and does not intervene, he or she could potentially be held liable if any harm results. In addition, few health care professionals would feel comfortable with the knowledge that they could have acted to prevent patient harm but did not do so. From a research point of view, however, intervention has three disadvantages. First, the nurse may not be given every chance to correct an error before the intervention, resulting in an artificially inflated error rate. Second, intervention could have an educational effect and prevent subsequent errors from occurring, although this does not always occur in practice (Dean *et al*, 1995; Ridge *et al*, 1995). Finally, unless carried out tactfully, intervention could introduce a judgemental dimension to the observation, resulting in distress to nursing staff and patients.

In recent UK studies, researchers have agreed that interventions are not appropriate in the case of U-MAEs (Dean *et al*, 1995; Ridge *et al*, 1995); however different approaches have been taken to O-MAEs. Ridge *et al* (1995) tactfully intervened to prevent all O-MAEs from reaching the patient. Interventions were timed to give the nurse every opportunity to correct the error, but made before the dose was given to the patient. However, Dean *et al* (1995) found that the researcher was not always able to prevent errors from occurring, and interventions were made for only 53% of the O-MAEs identified. Ho *et al* (1997) intervened only where MAEs were considered to represent a

significant risk to the patient; interventions were made for 7% of the O-MAEs identified. Given that the majority of MAEs are thought to have little propensity for harm, this approach may be justifiable as it should reduce any effect of intervention on the study's results yet avoid any ethical or medico-legal problems resulting from patient harm. It was therefore decided to adopt this strategy (intervening only where MAEs were considered to represent a significant risk to the patient) in the present study. To estimate any effect of the interventions themselves on error rates, it was also decided to calculate the O-MAE rates before and after the first intervention for each nurse.

9.5 Definition and classification of medication administration errors

In any quantitative study, it is essential that the events of interest are clearly defined, and that if incidence rates are quoted, the denominator used to calculate them is specified. To summarise, explain or draw conclusions from the data collected it is also important that events are classified in a meaningful way. However, inspection of published research suggests that there are nearly as many ways of defining and classifying MAEs as there are studies. In this next section, the definition of an MAE will first be discussed, before considering how MAE rates are calculated. The classification of MAEs will then be addressed.

9.5.1 Defining a medication administration error

An MAE is usually defined as a dose of medication that deviates from the physicians' written medication orders or from standard hospital policy (Allan and Barker, 1990). However, close examination of research reports reveals wide variation in the types of event considered MAEs. For example, in the UK, Ogden (1996) included cases where drugs were not given because a drug chart had not yet been written following patient admission; Gethins (1996) and Ogden (1996) both included errors in nurses' clinical judgement; Nixon (1995) included documentation errors. Such events are not considered MAEs by other UK researchers (Dean *et al*, 1995; Ridge *et al*, 1995; Ho *et al*, 1997). Similar variety exists amongst studies published in other countries. Some variation in

definitions results from different study objectives, some from different hospital policies and some from more arbitrary decisions. Whatever the reasons for them, these differences place severe limitations on the comparisons that can be made amongst published studies. What is unfortunate is not that such variation exists, but that many published reports contain insufficient detail to identify the precise criteria used.

Recognising that some standardisation was needed, in 1982 the American Society of Hospital Pharmacists published detailed definitions of different types of MAE (anonymous, 1982). However, even these definitions can be interpreted in different ways and they are insufficient for research use (Allan, 1987; Allan and Barker, 1990).

Four key areas of debate are whether administration time should be considered a source of error, how to define omission errors, how to address potential errors, and whether deviations from hospital procedures should be considered MAEs. Each of these issues will be considered in turn.

9.5.1.1 Wrong time errors

In the USA, a wrong time error has been defined as the administration of a dose more than a predefined time from its scheduled administration time (anonymous, 1993). It is recommended that the time window allowed is defined by the individual organisation; this is typically thirty or sixty minutes (Allan and Barker, 1990). In some European studies, a wrong time error has instead been defined as the administration of a dose during a different drug round to that intended (Jaubert de Beaujeu and Bureau, 1988; Mehrtens and Carstens, 1997).

Attitudes concerning the relative importance of wrong time errors vary. Barker *et al* (1966) contend that from a systems point of view, the early or late administration of medication represents a digression from a standard and should be considered an error. Others exclude wrong time errors, or record the time at which each dose is administered and analyse these data separately (Hynniman *et al*, 1970; Dean *et al*, 1995; Ridge *et al*, 1995).

There are several reasons why the inclusion of administration time as a source of error is potentially misleading. First, the interval between successive doses may be more important than the absolute time at which doses are administered, particularly for certain drugs (Lewis *et al*, 1996). Second, the correct administration of medication in relation to food may be more important than the hour at which a dose is given. Finally from a practical point of view, because wrong time errors can accompany other types of MAE, difficulties arise in maintaining mutually exclusive MAE categories. In the present study, it was therefore decided to exclude timing as a source of error. Even if a dose was given during a different drug round to that indicated on the drug chart, it was not considered an MAE.

9.5.1.2 Omission errors

An omission error is usually defined as a prescribed dose that has not been administered by the time the next dose is due (Allan and Barker, 1990). This definition generally includes doses omitted due to unavailability and those inadvertently omitted, but excludes doses omitted according to a nurse's clinical judgement, for example because a patient is nil-by-mouth. However, some US researchers have not attempted to identify omission errors, arguing that an observer would have to be constantly at each patient's bedside to be certain that the patient did not receive the medication (Means *et al*, 1975). This point is also relevant in UK studies, where observers generally attend only the scheduled drug rounds. If medication is unavailable during the drug round but obtained later, a dose may be given between scheduled drug rounds when the observer is not present.

In the present study, it was therefore decided to use patients' administration records to aid the identification of omission errors, as previously suggested by Borel and Rascati (1995; 1996). According to this method, where a dose is observed as being omitted during a drug round but the drug chart signed to indicate administration, it is assumed that the dose was not given. When doses are omitted but the corresponding section of the drug chart not signed, the observer examines the drug chart during subsequent rounds. If the chart is signed before the next dose is due, it is assumed that the dose concerned has been given between the drug rounds; this dose cannot be included in the study as its administration

has not been observed. However if the chart is not signed then it is assumed that an omission error has occurred and this dose therefore included. It has been suggested that using administration records in this way is incompatible with the observation-based technique (Allan and Barker, 1990; Gibson, 1996). However, unless a researcher shadows each nurse continually, it is the most practical alternative.

9.5.1.3 Potential errors

There is some controversy concerning how MAEs prevented by other health care professionals, the researcher or patients should be treated. Most studies exclude as errors those prevented by other health care professionals, although Nixon (1995) included those prevented by a second nurse. In most US studies any MAEs prevented by the researcher are excluded from the results. However, in UK studies where researchers routinely prevent errors from occurring, any errors so prevented are generally included in the analysis (Dean *et al*, 1995; Ridge *et al*, 1995).

Most studies exclude as MAEs those prevented by the patient. However, it could be argued that patients should not be relied on to prevent MAEs, as very unwell or confused patients are unlikely to be able to check the medication they are given. In addition, if the researcher intervenes, this may occur before the patient has had the opportunity to do so. Consequently, including errors prevented by the researcher but excluding those prevented by the patient is inconsistent.

In the present study, it was therefore decided to include in the analysis those MAEs prevented by patients or the researcher, but to exclude those prevented by other health care professionals.

9.5.1.4 Departures from hospital procedures

Researchers also vary in the attitudes taken to deviations from hospital policy or other recommended procedures. Barker (1966) does not consider the failure to follow procedures to be an MAE. However others consider as MAEs doses left at patients' bedsides, halved tablets, 'as required' drugs given before patients request them or the use

of 50 millilitre graduated cups to measure 5 millilitre doses (Allan and Barker, 1990; Nixon, 1995; Gethins, 1996; Ogden, 1996). Such events, while not representing ideal practice, do not fall within the definition of an MAE if the patient still receives the medication as prescribed.

In the present study, it was decided to adopt Barker's philosophy, and include as MAEs only those cases where the patient did not receive the medication according to the prescriber's administration instructions.

9.5.2 Calculating medication administration error rates

To calculate an MAE rate, a suitable denominator is required. In the first quantitative study of MAEs, Barker decided that the denominator should be the 'total opportunities for error', defined as all doses given plus any doses omitted (Barker and McConnell, 1962). This is equivalent to all doses ordered plus any unordered doses given. The rationale behind the use of this denominator, rather than the more intuitive 'number of doses ordered', was that it prevents the calculated error rate from exceeding 100%. All Barker's subsequent studies have used this method, although some other researchers have instead used the number of doses ordered (Tisdale, 1986; Nixon and Dhillon, 1996).

Although Barker wanted to prevent the error rate from exceeding 100%, it could be argued that if all ordered doses were given incorrectly and additional doses also given, an error rate of more than 100% would be meaningful. Other philosophical arguments for and against each method are best illustrated using examples. If observations were made for one thousand scheduled doses and five hundred errors identified, Barker's method would result in a 33% error rate if all the errors were unordered doses, but a 50% error rate if the errors were of any other type. The error rate therefore depends upon the type of error, with implicitly less importance placed on unordered dose errors. If the number of doses ordered was instead used as a denominator, the calculated error rate would be 50% in each case. However, if no doses were prescribed but five doses given, Barker's method would result in an error rate of 100%, while use of the number of doses ordered as the

denominator would result in division by zero. Both methods are therefore associated with theoretical problems. However, the examples given are extreme ones and the difference between the two methods for calculating MAE rates would be significant only if a substantial number of unordered doses were given. In addition, provided the denominator used is specified, the results of published studies can be adjusted to allow comparison with other studies if necessary (Allan, 1987; Allan and Barker, 1990). In the UK, most recent studies have used Barker's method (Dean *et al*, 1995; Cavell and Hughes, 1997; Ho *et al*, 1997; Ogden *et al*, 1997), one has used as a denominator the number of doses due (Nixon, 1995), while two do not specify the method used (Ridge *et al*, 1995; Gethins, 1996). In the present study, it was decided to use Barker's method with which to calculate percentage error rates, to facilitate comparison with previous studies.

Only those doses that the researcher observes and can classify as either correct or incorrect can be included as opportunities for error. Any dose that cannot be so classified should be excluded entirely; this includes cases in which the observer cannot determine what the prescriber intended (Barker *et al*, 1966). In the USA, many authors consider as opportunities for error only those doses that the patient is observed to consume (Allan and Barker, 1990). Doses left at the patient's bedside, whether correct or incorrect, are not included as opportunities for error if the researcher does not observe the patient taking the drug. However, in one study, any dose left at a patient's bedside was considered both an opportunity for error and an MAE as this practice was prohibited by hospital policy (Allan and Barker, 1990). In most UK hospitals, doses are frequently left at patients' bedsides for self-administration and only patients known to have problems taking medication are watched or helped by nursing staff. The exclusion of doses left at patients' bedsides as opportunities for error would therefore dramatically reduce the sample size. Watching patients consume each dose of medication is also incompatible with intervening to prevent harmful errors from reaching the patient and UK studies have therefore included doses left at patients' bedsides as opportunities for error. Dean *et al* (1995) analysed the results of their observation-based study both including and excluding doses left at patients' bedsides as opportunities for error. There was no significant difference between the two MAE rates calculated, suggesting that the inclusion of doses left at patients'

bedsides does not significantly affect the calculated error rate.

In the present study, it was therefore decided not to differentiate between doses whose consumption the researcher observed and those that were left with the patient. It was instead assumed that patients would take any medication left at their bedside by the nurse.

9.5.3 Classifying medication administration errors

MAEs have been classified in many different ways. The American Society of Health-System Pharmacists suggests nine categories: omission, wrong time, unauthorised drug, improper dose, wrong dosage form, wrong preparation technique, wrong administration technique (includes wrong route of administration), deteriorated drug and other error (anonymous, 1993). However, these categories are not necessarily mutually exclusive, an essential property of any classification system. For example, the wrong dose could be administered as a result of using the wrong preparation technique. Hynniman *et al* (1970) instead used only three categories: omission, commission and discrepancy. These authors defined an error of commission as any dose incorrectly administered and a discrepancy as any inconsistency or breakdown in the drug distribution system that did not result in an error of omission or commission. Most other researchers have used categories based on those described by the American Society of Health-System Pharmacists, although many differences amongst studies exist (Allan and Barker, 1990).

The most significant difference amongst studies relates to the classification of incidents in which a patient is prescribed one drug but given another. In most US studies, such cases are considered to be two medication administration errors: one unordered drug error and one omission error. Conversely, most UK authors consider such cases to be one wrong drug error (Dean *et al*, 1995; Gethins, 1996; Nixon and Dhillon, 1996). There are arguments in favour of each approach. Where the drug administered is similar to the drug prescribed, the most intuitive response may be to state that a wrong drug error has occurred. If the two are pharmacologically diverse, it may be more logical to state that an unordered drug error plus an omission error have occurred. However, counting two errors

when only one opportunity for error exists could be considered mathematically unsound, and it was therefore decided to consider each case to be one wrong drug error in the present study.

The above classifications all refer to the type of discrepancy between the medication prescribed and that administered; they give no indication of why the error occurred. Dean *et al* (1995) attempted to classify MAEs according to their most likely cause, but include both 'unclear prescription' and 'incorrect selection or preparation by nurse', which are not necessarily mutually exclusive. Few other researchers have attempted to classify the MAEs identified in observational studies according to their aetiology; the only distinction that has been made is between those that occur due to the unavailability of the drug concerned and those that occur for other reasons (Ridge, 1998). One of the problems associated with classifying MAEs according to cause is that it can only be speculative; without interviewing each person involved the observer cannot determine exactly why each error occurred. An alternative approach is to classify MAEs according to the stage of the drug distribution system in which they originate; this would also allow the most vulnerable parts of different drug distribution systems to be identified.

In the present study, it was therefore decided to classify errors according to both type of discrepancy and the stage of the drug distribution system in which they occurred.

Exhaustive and mutually exclusive categories were developed and piloted using data collected in previous studies; the categories developed will be specified in Chapter Ten.

9.6 Design of the trial

Having decided the data collection methods and definitions to be used, the next issue to be addressed was the experimental design of the trial itself.

The purpose of the trial was to determine the U-MAE and O-MAE rates associated with the traditional ward pharmacy system and a new drug distribution system, on the two study wards. A randomised controlled trial is generally considered to be the strongest experimental design. However the primary units of interest in the present study were

individual doses, which cannot readily be randomised to different drug distribution systems. Alternatives, such as the randomisation of patients or nurses to the different systems, were also considered impractical and it was concluded that a non-randomised controlled study was the only feasible option.

There are many factors that could have potentially significant, yet unmeasurable, effects on MAE rates and therefore had to be controlled for. These were considered to fall into two general groups: ward-related effects and time-related effects. Ward-related effects include differences in staff, patient populations and systems of work; these were considered to be specific to each ward but to be stable for the duration of the trial. Time-related effects include changes in hospital policy or pharmacy services; it was assumed that these could change during the trial but that they would have equivalent effects on each hospital ward.

In order to control for ward-related effects, it was decided that the two study wards should act as their own controls and that the MAE rates should be measured both before and after the introduction of the new system on each ward. To control for time-related effects, it was decided to implement the new system at different times on the two study wards (Robson, 1993). Five data collection periods were therefore required, as shown in figure 9.2.

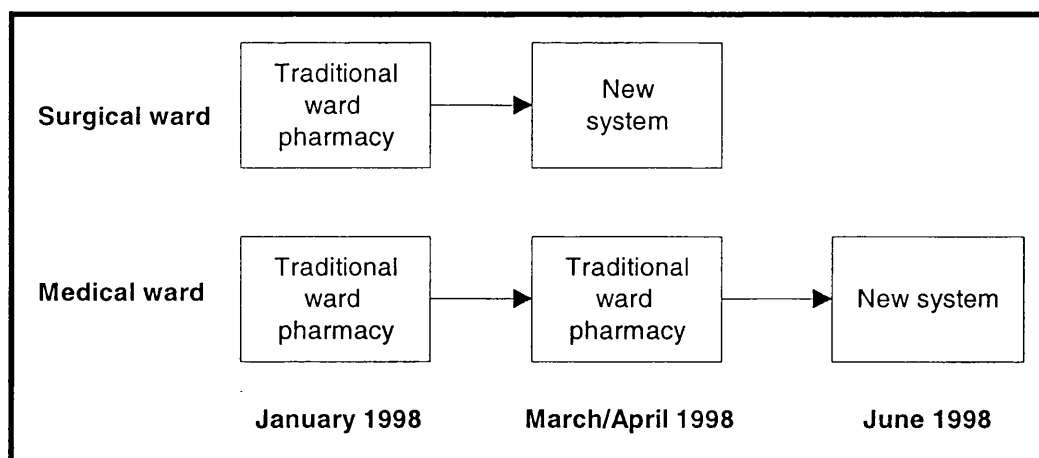


Figure 9.2 The trial's experimental design.

The repeated observation of the traditional ward pharmacy system on the medical ward would allow any time-related changes in the MAE rate to be identified; this would indicate whether any change in the surgical ward MAE rate could be attributed to factors other than the change in drug distribution system. Ideally, a second period of data collection would have been carried out in June for the new system on the surgical ward, but time constraints made this impossible.

In the next chapter, the precise methods used for the trial will be specified, before giving the results obtained.

Chapter Ten: Methods and results

10.1 Introduction

This chapter describes a study of unavailability-related medication administration errors (U-MAEs) and other medication administration errors (O-MAEs) associated with the traditional ward pharmacy system and a new drug distribution system. The aims of this trial were to investigate the impact of the new drug distribution system on MAEs, to evaluate the methodology adopted and to explore the predictive validity of the simulation model described in Chapter Five.

10.2 Objectives

1. To choose a new drug distribution system to test in practice on the two study wards.
2. To assess the effects of the new drug distribution system on the incidence and severity of MAEs.
3. To explore the potential impact of the methods used on the incidence of MAEs.
4. To compare the U-MAE rates that occur in practice with those predicted by the model.

10.3 Choice of a new drug distribution system

Eight different drug distribution systems were tested using the model (section 6.4); one of these had to be selected for implementation on the two study wards. The criteria used to select an appropriate system were as follows:

1. For each study ward it should have been predicted to reduce the U-MAE rate by a clinically meaningful amount.

2. It should be acceptable to the relevant pharmacy, nursing and medical staff.
3. It should cost less than £2000 to implement.

These criteria were intended to ensure that the system selected was potentially beneficial, practical and could be implemented within the project's timescale and budget.

Changes predicted to reduce the U-MAE rate by a meaningful amount (by more than 20% of the traditional ward pharmacy system U-MAE rate) on each ward were the writing of drug charts at pre-admission clinics, the use of patients' own drugs, the introduction of electronic prescribing, the extension of pharmacy opening hours and the extension of the residency service. The introduction of electronic prescribing was excluded on cost grounds. Discussion with ward and pharmacy staff revealed that a patients' own drugs (PODs) system was considered the most acceptable of the remaining alternatives. Some wards in the hospital had already implemented such a system and nursing staff on both study wards were keen to do likewise.

As well as having been predicted by the model to reduce U-MAEs, a PODs system has other potential advantages. If patients bring supplies of their own medication into hospital, it is easier for pharmacists and doctors to take accurate drug histories, and patients continue to receive brands of medication with which they are familiar. The current situation, in which patients' own medication is often destroyed, is avoided and wastage therefore reduced. Patients do not have to wait for further supplies of medication to be dispensed at discharge and there are financial advantages to the hospital. As a result, PODs systems are becoming widespread in the UK; in one hospital, all wards are now using this system (Semple *et al*, 1995). It has been suggested that PODs systems will also reduce the incidence of MAEs (John, 1997; John, 1998), but no studies have been carried out to establish if this is the case. It was therefore decided to implement a PODs system on the two study wards and measure the MAE rates before and after its introduction.

10.4 Methods

10.4.1 Description of the patients' own drugs system

A publicity campaign encouraging patients to bring their own medication into hospital was initiated on the two study wards and in the appropriate outpatient clinics. Whenever a patient was admitted to a study ward, nursing staff explained how the scheme worked and asked the patient to sign a consent form if they agreed to their own medication being used during their stay. Any medication brought in by the patient was then placed in a lockable bedside medicine cabinet, except for medication requiring refrigeration which was stored in the ward refrigerator. Patients' own supplies of controlled drugs were stored in their bedside medicine cabinets at the discretion of the nurse in charge. The ward pharmacist, during his or her next ward visit, checked that the patient's own medication was suitable for use (according to the criteria listed in Appendix 14), then endorsed the relevant sections of the drug chart with the words 'patient's own', the quantity of medication, the date and their signature. Any non-stock medication prescribed for which the patient did not have their own supply was dispensed in the pharmacy department. Similarly, if patients' own supplies of medication ran out, further supplies were dispensed.

During each scheduled drug round, nursing staff administered patients' own and individually dispensed medication from the bedside medicine cabinets and stock drugs from the drug trolley. If patients had their own supplies of drugs that were also ward stock, there was no policy regarding which supply should be used for administration. If patients' own medication had not yet been checked by the ward pharmacist, nurses could use their professional discretion in deciding whether or not to administer that medication against the doctor's medication order. For each ward, two master keys were supplied. These could open all the medicine cabinets on that ward but none on any other wards; one was kept by the nurse in charge and the other by the ward pharmacist.

10.4.2 Definitions

The definition and classification of MAEs were discussed in Chapter Nine; the following definitions were adopted for use during the trial.

10.4.2.1 Opportunity for error

An opportunity for error was defined as any regularly scheduled dose of medication that the researcher observed being administered (or omitted) and could classify as being either correct or incorrect. 'Administration' was taken to include leaving a dose at a patient's bedside for self-administration. Doses given between scheduled drug rounds and therefore not observed were not considered opportunities for error; all parenteral, topical and rectal doses were therefore excluded. Dietary supplements prescribed by the hospital dieticians were also excluded as opportunities for error. The total number of opportunities for error was used as the denominator with which to calculate percentage MAE rates.

10.4.2.2 Medication administration error

A medication administration error (MAE) was defined as a dose of medication administered (or omitted) that deviated from the patient's medication order as written on their drug chart. Pharmacists' written endorsements were considered part of the medication order. Administration of medication in relation to food was not assessed and failure to follow hospital procedures was not in itself considered an error. The time at which doses were administered was not considered a source of error. Errors prevented by the observer or the patient were included as MAEs for the purposes of this study, those prevented by other health care professionals were not.

MAEs were classified in two ways, first, according to type of discrepancy, and second, according to the stage of the drug distribution system in which they were considered to originate.

10.4.2.3 Types of medication administration error

The following categories of MAE were designed to be exhaustive and mutually exclusive;

each opportunity for error could be associated with only one MAE.

Omission

A dose of medication that had not been administered by the time of the next scheduled dose. Doses omitted according to doctors' instructions, according to a nurse's clinical judgement (including where the patient refused the medication or was designated nil-by-mouth) or because the patient was not on the ward were not considered opportunities for error.

Unordered drug

The administration of a dose of a drug that was not prescribed for the patient concerned. However, if drug X was prescribed but drug Y given instead, this was classified as a wrong drug error (see below).

Extra dose

The administration of an additional dose of a prescribed medication. This included the administration of a drug more times during the day than prescribed and the administration of an additional dose of a drug following its discontinuation.

Wrong drug

A dose of drug administered that was not the drug prescribed. However, generic substitution was not considered an error.

Wrong route

The administration of the correct drug by a route or site that was not that prescribed.

Wrong dose

The administration of the correct drug by the correct route but in a quantity that was not that prescribed. This included administration of the incorrect number of dose units, selection of the wrong strength of dose unit, and the measurement of an incorrect volume of an oral liquid. Where liquid preparations were not measured but instead poured into

ungraduated medicine cups, a wrong dose error was assumed to have occurred only where the researcher was certain that the wrong volume had been administered. If failure to shake a suspension resulted in a visible concentration gradient, this was also considered a wrong dose error.

Wrong pharmaceutical form

The administration of the correct dose of the correct drug by the correct route but in a formulation that was not that prescribed. This included the administration of a modified release¹ product when a non-modified release product was prescribed and vice versa. In the case of prednisolone, the administration of the enteric coated formulation against a prescription for plain prednisolone was considered neither an error nor an opportunity for error if the patient stated that they had been taking the enteric coated formulation prior to their admission. This is because medical staff often fail to specify that prednisolone is enteric coated when recording a patient's medication history. Appropriate purposeful alteration, such as substituting tablets with an equivalent soluble formulation or liquid to facilitate administration, was not considered an error.

Deteriorated drug

Administration of a drug that had exceeded its expiry date or for which the physical or chemical integrity has been compromised, where none of the above error types had occurred.

10.4.2.4 Stages of the drug distribution system in which MAEs originated

MAEs were first classified into those that occurred due to the unavailability of medication (U-MAEs) and those that occurred for any other reason (O-MAEs). Each of these categories had further sub-divisions, as shown in figure 10.1. The categories used were exhaustive and mutually exclusive; each is explained in more detail below.

¹

A modified release tablet or capsule is formulated to control or delay the release of the active drug. Such formulations can be used to release the drug throughout the day, thus reducing the number of daily doses that are required.

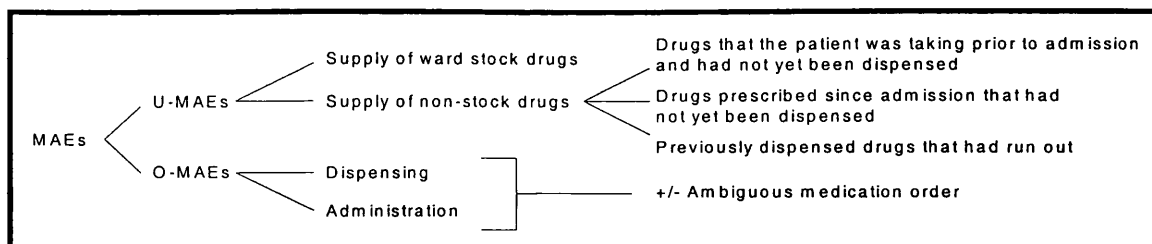


Figure 10.1 Classification of medication administration errors according to the stage of the drug distribution system in which they originated.

U-MAEs

Any error that occurred due to unavailability of the medication concerned was considered a U-MAE. U-MAEs were therefore almost always omission errors. U-MAEs were classified into those that occurred due to unavailability of stock medication and those that occurred due to unavailability of non-stock medication. This latter group was further subdivided into those that occurred due to the unavailability of drugs that the patient had been taking prior to their admission and had not yet been dispensed, those that occurred due to the unavailability of drugs that had been prescribed during the patient's hospital stay but had not yet been dispensed, and those that occurred due to the unavailability of drugs that had previously been dispensed.

O-MAEs

A medication error that occurred for any reason other than unavailability was considered an O-MAE. O-MAEs were further subdivided into those that originated in the dispensing process and those that originated in the administration process.

Any medication order that, in the observer's judgement, contributed to the occurrence of an O-MAE because of the way in which it was written, was considered an ambiguous medication order. This included illegible handwriting and the prescription of medication using non-standard or confusing nomenclature. 'Ambiguous medication order' was therefore considered an additional factor that could contribute to the occurrence of O-MAEs in the dispensing or administration stages of the drug distribution system.

10.4.3 Preparation for the study

Details of the proposed data collection methods were sent to the chairman of the relevant Local Research and Ethics Committee (LREC). He indicated that the study would be considered audit and a submission to the LREC therefore unnecessary. The hospital's Nursing Research and Ethics committee gave their approval for the study.

Prior to the first data collection period, the researcher met with nursing staff on both study wards and explained how the new system would operate and how it would be evaluated. Before each of the five data collection periods, the sister in charge of the ward concerned was sent a memo specifying the dates between which the data collection was to take place. It was also emphasised that names of individual nurses, patients or wards would not be identifiable from the results and that if any nurse preferred not to be observed, this decision would be respected.

10.4.4 Choice of sample size

The primary objective of the trial was to assess the effects on MAEs of introducing a PODs system. The sample size required was therefore calculated based on the overall MAE rate. It was anticipated that the introduction of the PODs system would reduce the overall MAE rate; the model predicted a reduction in U-MAEs and it has been suggested that other types of error would also be decreased (John, 1997; John, 1998). Previous research in the study hospital suggested that an overall MAE rate of between 3.0% and 8.0% could be expected with the traditional ward pharmacy system (Dean *et al*, 1995; Taxis, 1997); halving the MAE rate was taken to represent a clinically significant change. If a reduction from 3.0% to 1.5% was to be statistically significant using α (the probability of making a type I error) of 0.05 and β (the probability of making a type II error) of 0.2, at least 1532 opportunities for error were required in each of the five data collection periods (Campbell *et al*, 1995). This sample size would also mean that a reduction from 8.0% to 5.5% would be statistically significant. Achieving this sample size for each of the five data collection periods, rather than for each drug distribution

system, would allow any significant ward-related or time-related differences in the MAE rate to be identified. Furthermore, if the samples for the two wards were combined, the power to detect a clinically significant difference between the two drug distributions systems would be about 98%. A sample of 1532 opportunities for error in each data collection period was thought to be a realistic goal; based on pilot work, it was anticipated that seven days of observation would be required during each data collection period on the surgical ward, and ten on the medical ward.

10.4.5 Data collection methods

The two study wards were described in Chapter Four. Briefly, the surgical ward had 28 beds and specialised in vascular surgery; the medical ward had 16 beds and specialised in renal medicine. On each ward, all 8 am doses were administered during the 6 am drug round and all 2 pm doses at noon. The traditional ward pharmacy system was studied on the surgical ward from 12th to 18th January, and on the medical ward from 26th January to 4th February and from 16th to 25th March 1998. The PODs system was observed on the surgical ward from 2nd to 8th April and on the medical ward from 1st to 10th June 1998.

All scheduled drug rounds (6 am, noon, 6 pm and 10 pm) were observed daily during each of the five data collection periods; weekends were included. A second observer, who had previous experience of observation-based MAE research, assisted with data collection. All methods and definitions were standardised between the two observers. Each observer was allocated two drug rounds each day so that for each data collection period, the number of 6 am, noon, 6 pm and 10 pm rounds observed were approximately equal for each observer. To reduce observer fatigue, rounds were allocated so as to minimise the number of times the same observer was scheduled to observe a 10 pm drug round followed by a 6 am drug round.

Immediately prior to each drug round, the observer identified the nurse who would be conducting the drug round, introduced herself and asked if she could accompany the nurse

during the round. If the nurse was willing to be observed, the observer recorded details of all doses administered and all doses ordered on a preprinted data collection form (Appendix 15). If the observer was not able to see the drug chart and the medication administered at the same time, she recorded details of the doses administered and then examined the drug chart at a later stage. Any discrepancies between the medication prescribed and that administered were identified and their details recorded. The identity of the nurse was recorded in coded form.

As discussed in Chapter Nine, where a dose was omitted during a drug round but the drug chart signed to indicate administration, it was assumed that the dose was never given. Where a dose was omitted and the corresponding section of the drug chart not signed, the observer examined the drug chart during subsequent rounds. If the chart was signed before the next dose was due, it was assumed that the dose concerned had been given; this dose was not included as an opportunity for error as its administration had not been observed. However if the chart was not signed, the dose concerned was included as both an opportunity for error and an omission error.

If, in the observer's judgement, a patient was likely to suffer harm as a result of an error, she tactfully intervened to prevent the patient from consuming the dose concerned. In general, no interventions were made for doses omitted due to drug unavailability or where errors were not identified until after administration.

At the end of each data collection period, a record was made of the number of doses due for which a cross was documented on the drug chart (indicating that the dose concerned had been omitted), and the number of crosses for which a corresponding reason was given. Similar chart audits were carried out on each ward for periods that had not been observed.

During each PODs system data collection period, the number of patients who brought in supplies of their own medication was determined.

10.5 Data analysis

Data analysis will be described in three sections corresponding to the trial's objectives, which were to assess the effects of the PODs system on the incidence and severity of MAEs, to evaluate the methods used and to compare the U-MAE rates obtained in practice with those predicted by the model.

10.5.1 The incidence and severity of medication administration errors

10.5.1.1 The incidence of MAEs

To investigate the effects of the PODs system on MAE rates, the following null hypotheses were tested; in each case the alternative hypothesis was that there was a difference.

1. The introduction of a PODs system had no effect on the incidence of MAEs.
2. The introduction of a PODs system had no effect on the U-MAE rate.
3. The introduction of a PODs system had no effect on the O-MAE rate.

The overall MAE rate and its 95% confidence interval (Gardner and Altman, 1989) were calculated for each of the five data collection periods; separate U-MAE and O-MAE rates were also calculated. Chi square tests were used to test each hypothesis. MAEs were then classified according to their type and the stage of the drug distribution system in which they occurred.

10.5.1.2 The severity of MAEs

To explore the effects of introducing a PODs system on MAE severity, the following null hypothesis was tested:

1. The introduction of a PODs system had no effect on MAE severity.

The severity assessment method developed in Chapter Eight was applied to the MAEs

identified. A brief description was produced of each MAE identified. Where the same error was repeated in the same patient, the errors were listed together as one case. Where identical errors had occurred in similar patients, only one example of each was included in the cases listed, however all errors were included in the final analysis. This was to minimise the judges' workload. The resulting cases were listed in a random order before being sent to the judges, so that it was impossible to determine which had occurred with the PODs system and which with the traditional ward pharmacy system.

A senior nurse, a senior doctor and two senior pharmacists were asked to score the severity of each MAE case using a scale numbered from zero to ten, as previously described (section 8.3.1). The judges were asked to assess the cases in sets of fifty to minimise fatigue and to record the time taken to score each set. Each judge was paid £150 for their participation.

For each MAE case, the mean score across all four judges was calculated and used as its index of severity. The randomisation was then reversed and the mean severity score calculated for each ward and each drug distribution system. The numbers of cases with scores between 3 and 7 (representing those likely to be associated with moderate outcomes), and above 7 (representing those likely to be associated with severe outcomes), were also determined. An analysis of variance was then used to compare the scores for each drug distribution system and each ward. The severity scores for those MAEs in which the observer intervened were also calculated and compared to the scores for those in which no interventions were made.

10.5.2 Evaluation of the methodology

Two aspects were considered. The first was the trial's experimental design, the second was the potential effect on MAEs of the observational method adopted.

10.5.2.1 Experimental design

Since the trial was not randomised, it was important to identify potential confounding

factors that could have affected the MAE rates identified. As previously discussed, it was anticipated that there could be both time-related and ward-related effects on MAEs; these were taken into account during the selection of the trial's experimental design. Other potential sources of variation in MAE rates were the different observers, the different nurses responsible for medication administration, the different days of the week and the different times of day. It was therefore considered essential to explore all of these issues. Since each of these factors could have different effects on U-MAEs and O-MAEs, it was decided to examine the U-MAE and O-MAE rates separately.

The following null hypotheses were tested:

1. There was no difference between the two traditional system data collection periods on the medical ward in terms of their U-MAE rates.
2. There were no ward-related differences in U-MAE rates.
3. There was no difference between the U-MAE rates detected by the two observers.
4. There was no difference amongst nurses in terms of their U-MAE rates.
5. There was no difference in terms of U-MAE rates amongst the different days of the week.
6. There was no difference in terms of U-MAE rates amongst the different drug round times.
7. There was no difference between the two traditional system data collection periods on the medical ward in terms of their O-MAE rates.
8. There were no ward-related differences in O-MAE rates.
9. There was no difference between the O-MAE rates detected by the two observers.
10. There was no difference amongst nurses in terms of their O-MAE rates.
11. There was no difference in terms of O-MAE rates amongst the different days of the week.
12. There was no difference in terms of O-MAE rates amongst the different drug round times.

MAEs that occurred due to unavailability (U-MAEs)

The U-MAE rates for the two traditional ward pharmacy system data collection periods on the medical ward were compared using a chi square test, to identify any time-related changes in the U-MAE rate. Further univariate analyses, also using chi square tests, were then carried out to investigate how the ward, observer, nurse, day of the week and time of drug round affected the frequency with which U-MAEs occurred. As multiple comparisons were being made, the Bonferroni correction (Bryman and Cramer, 1997) was used and a significance level of 0.008 adopted¹. Finally, to separate the effects of each variable and explore any relevant interactions, a multivariate logistic regression analysis was carried out (Armitage and Berry, 1994). The dependent variable was the probability of a U-MAE occurring.

MAEs that occurred for other reasons (O-MAEs)

The univariate and multivariate analyses described above were repeated for the O-MAEs.

10.5.2.2 Testing the effects of observation on MAEs

To investigate the potential effects of the observation and the observers' interventions, the following null hypotheses were tested:

1. There was no change in the O-MAE rate with repeated observation.
2. There was no difference between observed and unobserved periods in terms of the proportion of crosses on the drug charts for which a reason was documented.
3. There was no change in the O-MAE rate following intervention by the observer.

As explained in section 9.4.1.2, it was assumed that if observation or intervention had any effect on MAEs, this would be most apparent in the O-MAE rate. Each drug round was classified as being the first, second or third (and so on) observed round for the nurse concerned. An O-MAE rate was calculated for all of the first observed rounds, all of the second observed rounds, and so on. A logistic regression analysis with a polynomial contrast was then used to identify any change in the O-MAE rate with repeated

¹ 0.008 = 0.05 ÷ 6

observation. The dependent variable was the probability of an O-MAE occurring.

The proportion of crosses on the drug charts (indicating omitted doses) for which a reason was documented was calculated for the observed periods and the unobserved periods, and a chi square test used to identify any difference between them.

For each nurse with whom an intervention was made, the O-MAE rate up to and including the first intervention was calculated. The pre-intervention O-MAE rate for all the nurses with whom an intervention was made was then compared with the post-intervention O-MAE rate for the same nurses, using a chi square test.

10.5.3 Comparison of the U-MAE rates identified in practice with those predicted by the model

For each ward, the U-MAE rate identified during the trial was compared to that predicted by the model and the reasons for any differences explored. The following null hypotheses were tested:

1. Following the implementation of the PODs system, the real world U-MAE rates changed in the same direction as predicted by the model.
2. There were no differences between the U-MAE rates identified during the trial and those predicted by the model.

10.6 Results

10.6.1 Overview

Twenty-eight drug rounds were observed during each data collection period on the surgical ward, and forty during each on the medical ward. Due to observer error, the Saturday 6 am drug round was not observed during the traditional ward pharmacy system data collection period on the surgical ward. An additional 6 am drug round was therefore

observed the following Monday. All the nurses involved agreed to be observed.

Following the implementation of the PODs system, 12 (52%) of the 23 patients admitted to the surgical ward were taking medication prior to their admission; of these, 7 (58%) brought in supplies of their own drugs. On the medical ward 16 (75%) of the 21 patients admitted were taking medication prior to their admission; 10 (76%) brought in supplies of their own drugs. However, three of these patients administered their own medication during their hospital stay and their doses could not be observed. Of the patients observed, 54% of those who were taking medication prior to their admission had supplies of their own drugs.

10.6.2 The incidence and severity of medication administration errors

10.6.2.1 The incidence of MAEs

Overall, 6104 opportunities for error and 294 MAEs were observed. However, 37 of these were wrong dose errors resulting from the measurement of Gaviscon liquid or lactulose elixir using ungraduated paper medicine cups. These incidents occurred most often on the medical ward, where graduated measuring cups were apparently unavailable. Patients were typically administered about 20 millilitres when 10 millilitres was prescribed, or vice versa. Discussion with medical staff revealed that the prescription of 10 millilitres or 20 millilitres of these medicines was usually arbitrary, and it was therefore decided to exclude these opportunities for error from the analysis. Figure 10.2 summarises the overall MAE rates identified following the exclusion of these incidents; table 10.1 shows the opportunities for error, U-MAEs and O-MAEs observed during each data collection period. These data include ten errors (3.9% of all MAEs) prevented by patients; six of these occurred on the surgical ward (one in the traditional ward pharmacy system and five in the PODs system) and four on the medical ward (three in the traditional system and one in the PODs system). A description of each MAE is given in Appendix 16; an account of other incidents of interest that could not be classified as MAEs is given in Appendix 17. The sample size obtained was slightly smaller than anticipated as a result of having to exclude such opportunities for error from the analysis.

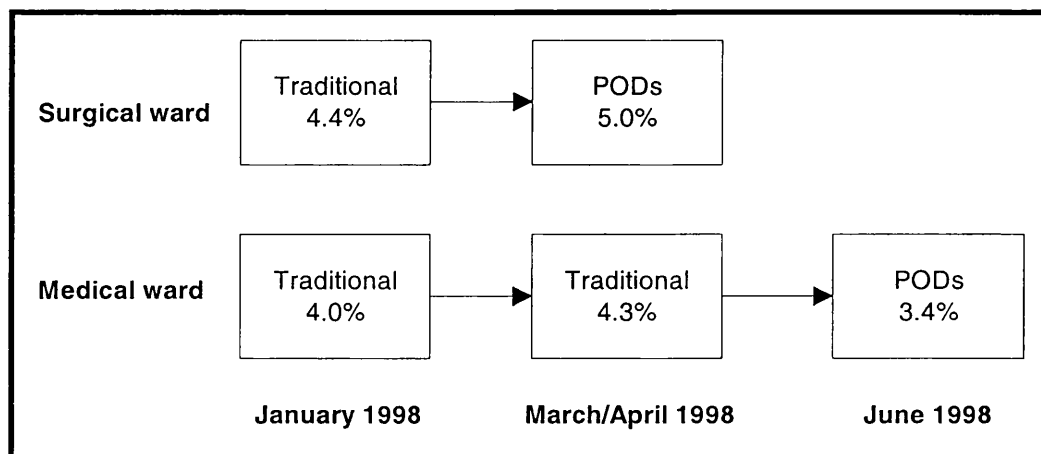


Figure 10.2 Summary of the trial's results.

Percentages relate to the overall MAE rates identified in each data collection period.

Ward	System	OE	Unavailability-related MAEs				Other MAEs				Total MAEs		
			U-MAEs	U-MAE rate	95% CI *	O-MAEs	O-MAE rate	95% CI *	MAEs	MAE rate	MAE	95% CI *	
Surgical	Traditional	1510	24	1.6%	1.0 to 2.2%	42	2.8%	2.0 to 3.6%	66	4.4%		3.4 to 5.4%	
Surgical	PODs	1279	30	2.3% [†]	1.5 to 3.1%	34	2.7% [†]	1.8 to 3.6%	64	5.0% [†]		3.8 to 6.2%	
Medical	Trad. (1)	1071	11	1.0%	0.3 to 1.5%	32	3.0%	2.0 to 4.0%	43	4.0%		2.8 to 5.2%	
Medical	Trad. (2)	995	18	1.8%	1.0 to 2.6%	25	2.5%	1.5 to 3.5%	43	4.3%		3.0 to 5.6%	
Medical	Trad. (total)	2066	29	1.4%	0.9 to 1.9%	57	2.8%	2.1 to 3.5%	86	4.2%		3.3 to 5.0%	
Medical	PODs	1212	12	1.0% [†]	0.4 to 1.6%	29	2.4% [†]	1.5 to 3.3%	41	3.4% [†]		2.4 to 4.4%	

Table 10.1 Opportunities for error (OE) and medication administration errors (MAEs) observed in each phase of the trial, excluding lactulose and Gaviscon wrong dose errors (see text).

* CI: confidence interval.

[†] non-significant difference between traditional ward pharmacy system and PODs system.

The differences in MAE rates between the two traditional ward pharmacy system data collection periods on the medical ward were not statistically significant. Data from the two data collection periods were therefore combined before subsequent analysis.

The overall MAE rate for the traditional system was 4.3%; for the PODs system it was 4.2%. This difference is not statistically different ($p = 0.99$; chi square test). Similarly, there were no differences in terms of U-MAEs or O-MAEs ($p = 0.28$ and 0.63 respectively; chi square tests). If the data are analysed separately for each ward, there is no significant difference between the two drug distribution systems in terms of overall MAEs ($p = 0.48$ and 0.31 for the surgical and medical wards respectively), U-MAEs ($p = 0.19$ and 0.39) or O-MAEs ($p = 0.93$ and 0.60).

Figure 10.3 shows the types of MAE identified during each phase of the study. There was no difference between the traditional ward pharmacy system and the PODs system in terms of the types of MAE that occurred ($p = 0.19$; chi square test).

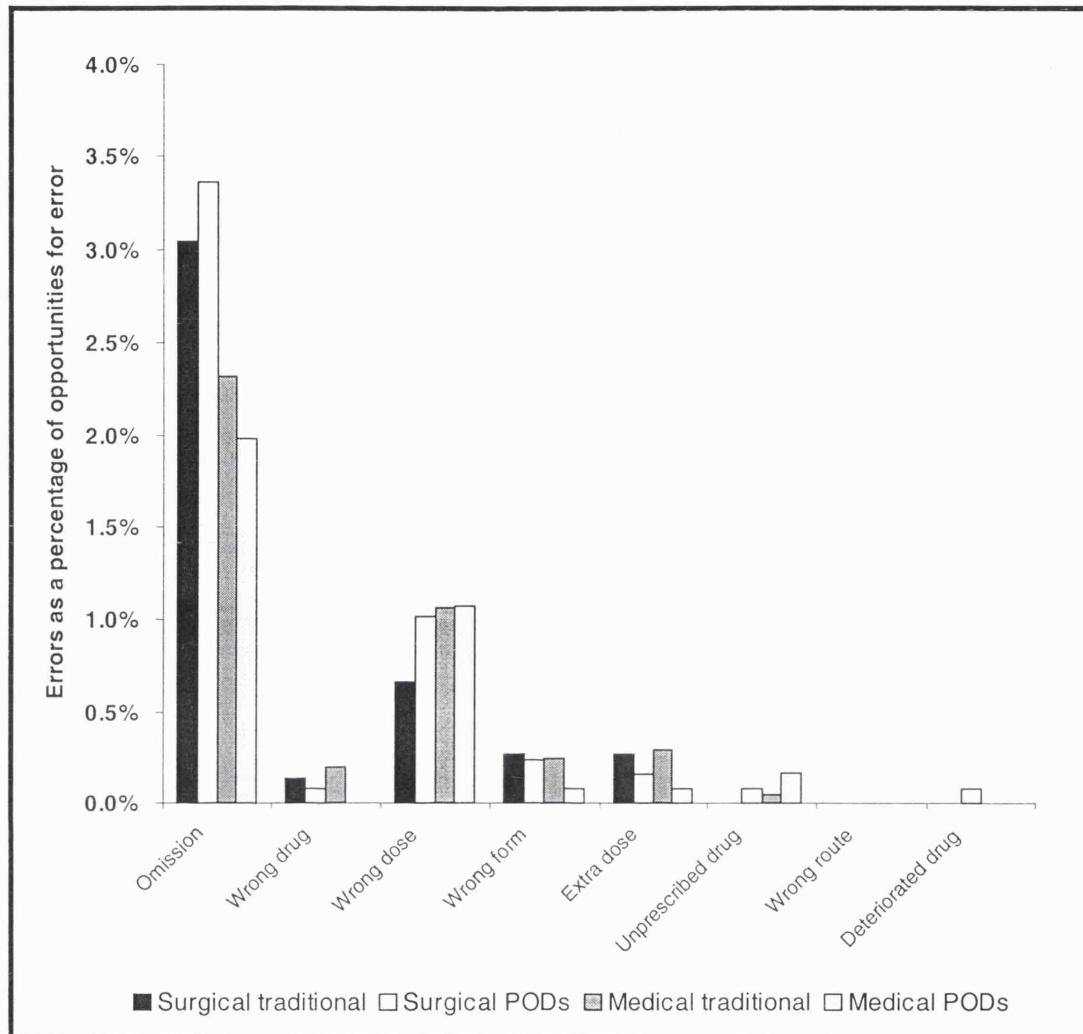


Figure 10.3 Types of medication administration error identified during each phase of the trial.

Overall, U-MAEs accounted for 59% of the omissions that occurred. The different types of U-MAE identified during each data collection period are shown in table 10.2. Overall, the most common type of U-MAE was the unavailability of medication that had been prescribed subsequent to the patient's admission but had not yet been dispensed. On the surgical ward, however, surprisingly high numbers of U-MAEs occurred due to the exhaustion of supplies of previously dispensed medication.

Ward	System	Stock drugs	Non-stock drugs			Total
			Taken on admission	Newly prescribed	Previously dispensed	
Surgical	Traditional	1 (0.07%)*	3 (0.20%)	7 (0.46%)	13 (0.86%)	24
Surgical	PODs	4 (0.31%)	10 (0.78%)	6 (0.47%)	10 (0.78%)	30
Medical	Traditional	0 (0%)	7 (0.34%)	19 (0.92%)	3 (0.15%)	29
Medical	PODs	0 (0%)	2 (0.17%)	9 (0.74%)	1 (0.08%)	12
TOTAL		5	22	41	27	95

Table 10.2 Types of U-MAE identified during each phase of the trial.

* Expressed as a percentage of the opportunities for error.

All of the O-MAEs identified originated in the administration stage of the drug distribution system; none originated in the dispensing stage. In the researcher's opinion, ambiguous medication orders contributed to thirty-six (22%) of the O-MAEs identified.

Figure 10.4 summarises the stages of the drug distribution system in which the MAEs originated. There was no difference between the traditional ward pharmacy system and the PODs system in terms of the stages involved ($p = 0.17$; chi square test).

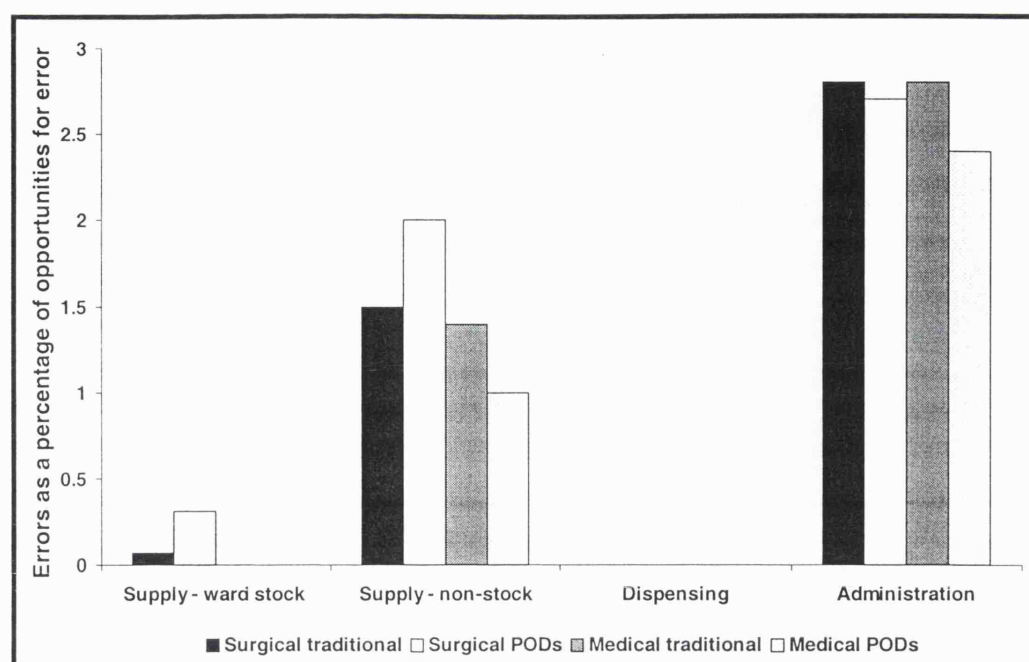


Figure 10.4 Stages of the drug distribution system in which medication administration errors originated.

Table 10.3 summarises the results relating to the incidence of MAEs according to the hypotheses tested.

Null hypothesis	Accepted/Rejected (p value)*
The introduction of a PODs system had no effect on the incidence of MAEs.	Accepted (p = 0.99)
The introduction of a PODs system had no effect on the U-MAE rate.	Accepted (p = 0.28)
The introduction of a PODs system had no effect on the O-MAE rate.	Accepted (p = 0.63)

Table 10.3 The incidence of MAEs: the hypotheses tested.

* Chi square tests

10.6.2.2 The severity of MAEs

The 257 MAEs identified were represented as 188 cases (some cases represented more than one error). All four judges assigned severity scores to all 188 cases. The two

pharmacists took 74 and 100 minutes respectively to score all the cases, the doctor 80 minutes and the nurse 180 minutes (median 90 minutes). Severity scores relating to each phase of the trial are summarised in table 10.4; the scores given to each case are indicated in Appendix 16. Overall, 16% of the MAE cases had moderate severity scores; none were considered severe. Examples of cases with minor and moderate severity scores are shown in table 10.5.

Ward	System	Cases	Mean score	SD *	Min score	Max score	Cases with moderate severity scores [†] (%)
Surgical	Traditional	44	1.8	1.1	0	4.6	6 (14%)
Surgical	PODs	45	1.8	1.1	0	4.4	6 (13%)
Medical	Traditional	65	2.1	1.1	0.4	5.6	13 (20%)
Medical	PODs	34	1.9	1.0	0.3	3.9	6 (18%)
TOTAL		188	1.9	1.1	0	5.6	31 (16%)

Table 10.4 Severity scores for MAE cases identified during each phase of the trial.

* SD: Standard deviation

[†] Scores between 3.0 and 7.0 suggest that an MAE would have an outcome of moderate severity.

The scores for each of the four phases could be considered normally distributed ($p > 0.05$ for medical ward traditional system, $p > 0.15$ for the others; Kolmogorov-Smirnov test) and variances were equal ($p = 0.97$; Levene test). A factorial analysis of variance suggested that there were no differences in severity scores between the two drug distribution systems ($p = 0.41$) or between the two study wards ($p = 0.22$). Neither was there any interaction between ward and system ($p = 0.68$). When the proportions of cases with moderate outcomes were considered, there was no difference amongst the four phases of the trial ($p = 0.75$; chi square test).

The nineteen cases in which interventions were made had a mean severity score of 2.7 (standard deviation 1.5); the cases for which no interventions were made had a mean score of 1.8 (standard deviation 1.0). This difference is statistically significant ($p = 0.03$; t-test for two samples with unequal variances), implying that interventions were not made for the less severe errors.

Minor severity	Moderate severity
Surgical ward, traditional ward pharmacy system	
A patient with hyperlipidaemia and ischaemic heart disease was prescribed pravastatin 20mg once daily. One dose was omitted.	A patient with severe asthma was prescribed nebulised salbutamol 2.5mg four times daily. One morning she received instead a dose of 5ml 0.9% sodium chloride.
An elderly lady with glaucoma was prescribed timolol 0.5% eye drops once daily to the right eye. Two doses were omitted on two consecutive days.	An elderly lady with angina was prescribed amlodipine 5mg once daily. One dose was omitted.
A patient with gastro-oesophageal reflux was prescribed cisapride 10mg three times daily. The first dose was omitted.	A patient with angina was prescribed isosorbide mononitrate 20mg three times daily. One dose of amlodipine 20mg was instead given.
Surgical ward, patients' own drugs system	
A patient was receiving ascorbic acid 200mg once daily. One dose of 100mg was administered.	A patient was prescribed four prophylactic doses of sodium fusidate 500mg three times daily after orthopaedic surgery. She did not receive any of this medication.
A patient with congestive heart failure was prescribed enalapril 10mg twice daily. One dose was omitted.	A patient was prescribed metronidazole 400mg three times daily for the treatment of a post-operative infection. Three doses were omitted after four days of treatment.
A patient with hypertension was prescribed losartan 75mg once daily. On two consecutive days, only 50mg was given.	A patient with a clotting disorder was prescribed vitamin K injection, 10mg once daily. Instead she received one Sando K tablet (potassium chloride 12 mmol).
Medical ward, traditional ward pharmacy system	
A patient with a previous renal transplant was prescribed prednisolone 10mg three times a week (Mondays, Wednesdays and Fridays). Two extra doses were given on the Tuesday and the Thursday.	An elderly lady with chronic renal failure was prescribed nifedipine LA 90mg once daily. One two consecutive days she was given instead nine nifedipine SR 10mg tablets.
A patient with chronic renal failure was prescribed one Calcichew tablet (calcium carbonate 1.25g) three times a day as a phosphate binding agent. One dose of two tablets was given.	A patient admitted with rejection of a renal transplant was prescribed prednisolone 48mg once daily. One dose of 0.5mg was given.

Table 10.5 continues overleaf

Continued from previous page

A patient with chronic renal failure and CAPD*-related peritonitis was prescribed co-amoxiclav 325mg three times daily. One the second day of the course he was given a dose of 625mg.

An immunosuppressed patient with a mycoplasma infection was prescribed doxycycline 100mg once daily. The first dose was omitted.

Medical ward, patients’ own drugs system

A patient with chronic renal failure was prescribed lansoprazole 15mg twice daily for the treatment of dyspepsia. One dose of 30mg was instead given.

A patient was taking sotalol 80mg twice daily for the treatment of cardiac arrhythmias. One dose was omitted.

A patient with chronic renal failure suffering from nausea and vomiting was taking oral cyclizine 50mg three times daily. One dose was omitted.

A patient with an ulcerated tongue was prescribed Difflam mouthwash (benzylamine hydrochloride), 10ml four times a day. The first four doses were omitted.

A patient with a previous renal transplant was prescribed alfacalcidol 0.5mcg daily. One dose of 0.25mcg was given.

A patient with a previous renal transplant was prescribed tacrolimus 8mg twice daily. One dose of 6mg was given.

Table 10.5 Some examples of MAE cases given minor and moderate severity scores.

* CAPD: Continuous ambulatory peritoneal dialysis

Table 10.6 summarises the findings relating to MAE severity according to the hypothesis tested.

Null hypothesis	Accepted/Rejected (p value)*
The introduction of a PODs system had no effect on MAE severity.	Accepted (p = 0.41)

Table 10.6 MAE severity: the hypothesis tested.

* Analysis of variance

10.6.3 Evaluation of the methodology

10.6.3.1 Experimental design

MAEs that occurred due to unavailability (U-MAEs)

There was no difference between the two ward pharmacy system data collection periods on the medical ward in terms of their U-MAE rates (table 10.1) ($p = 0.19$; chi square test). Neither was there a significant effect of ward ($p = 0.04^1$), observer ($p = 0.70$) or nurse ($p = 0.13$). However, there was a significant difference in the U-MAE rates identified on different days of the week ($p = 0.008$) and at different times of day ($p = 0.003$). The results of these analyses are presented in tables 10.7 to 10.11.

Ward	OE	U-MAEs	U-MAE rate
Surgical	2789	54	1.94%
Medical	3278	41	1.25%

Table 10.7 U-MAE rates identified for each ward.

The difference between wards is not significant ($p = 0.04$; chi square test)¹.

Observer	OE	U-MAEs	U-MAE rate
1	3025	45	1.49%
2	3042	50	1.64%

Table 10.8 U-MAE rates identified by each observer.

The difference between observers is not significant ($p = 0.70$; chi square test).

¹

According to the Bonferroni correction, a significance level of 0.008 was adopted.

Nurse	OE	U-MAEs	U-MAE rate
A	81	1	1.23%
B	90	0	0.00%
C	216	6	2.78%
D	630	2	0.32%
E	393	9	2.29%
F	38	1	2.63%
G	468	10	2.14%
H	637	13	2.04%
I	523	13	2.49%
J	258	8	3.10%
K	63	1	1.59%
L	117	4	3.42%
M	66	0	0.00%
N	12	1	8.73%
O	187	1	0.53%
P	484	5	1.03%
Q	235	1	0.43%
R	14	0	0.00%
S	13	0	0.00%
T	89	1	1.12%
U	260	4	1.54%
V	315	4	1.27%
W	45	1	2.22%
X	301	4	1.33%
Y	165	1	0.61%
Z	137	2	1.46%
AA	230	2	0.87%

Table 10.9 U-MAE rates identified for each nurse.

The difference amongst nurses is not significant ($p = 0.13$; chi square test).

Day	OE	U-MAEs	U-MAE rate
Monday	1104	14	1.27%
Tuesday	1001	15	1.50%
Wednesday	995	14	1.41%
Thursday	685	8	1.17%
Friday	770	25	3.25%
Saturday	695	11	1.58%
Sunday	817	8	0.12%

Table 10.10 U-MAE rates identified for each day of the week.

The difference amongst the days of the week is significant ($p = 0.008$; chi square test).

Time of round	OE	U-MAEs	U-MAE rate
6 am	3026	39	1.29%
noon	764	24	3.14%
6 pm	1154	15	1.30%
10 pm	1123	17	1.51%

Table 10.11 U-MAE rates identified for each drug round time.

The difference amongst the drug round times is significant ($p = 0.003$; chi square test).

A logistic regression analysis confirmed that ward, observer and nurse had no effect on the U-MAE rate ($p = 0.07$, 0.80 and 0.14 respectively) and that day of week and time of day had significant effects ($p = 0.02$ and 0.007 respectively). Drug rounds on Fridays and at noon had higher U-MAE rates than those at other times. In comparison to Monday, the odds ratio for Friday was 2.4 (95% confidence interval 1.2 to 4.7). The reason for this is unclear as the types of U-MAE were the same on Fridays as on other days of the week ($p = 0.50$; chi square test). In comparison to 6 am rounds, the odds ratio for noon rounds was 2.3 (95% confidence interval 1.4 to 3.9). This was mainly attributable to an increase in the numbers of omissions of ward stock medication. A logistic regression analysis confirmed that the drug distribution system used had no effect on the U-MAE rate ($p = 0.73$). The interaction effects 'ward by drug distribution system' and 'ward by day' were also investigated, but neither had a significant effect on the U-MAE rate ($p = 0.09$ and $p =$

0.93 respectively). Appendix 18 presents more detailed results of the logistic regression analysis.

Table 10.12 summarises the results of these analyses according to the hypotheses tested.

Null hypothesis	Accepted/Rejected (p value)
There was no difference between the two traditional system data collection periods on the medical ward in terms of their U-MAE rates.	Accepted (p = 0.19)*
There were no ward-related differences in U-MAE rates.	Accepted (p = 0.07) [†]
There was no difference between the U-MAE rates detected by the two observers.	Accepted (p = 0.80) [†]
There was no difference amongst nurses in terms of their U-MAE rates.	Accepted (p = 0.14) [†]
There was no difference in terms of U-MAE rates amongst the different days of the week.	Rejected (p = 0.02) [†]
There was no difference in terms of U-MAE rates amongst the different drug round times.	Rejected (p = 0.01) [†]

Table 10.12 U-MAEs: the hypotheses tested.

* Chi square test

[†] Logistic regression analysis.

MAEs that occurred for other reasons (O-MAEs)

There was no difference between the two ward pharmacy system data collection periods on the medical ward in terms of their O-MAE rates (table 10.1) (p = 0.60; chi square test). There was also no difference between wards (p = 0.87), observers (p = 0.12), days of the week (p = 0.01¹) or times of day (p = 0.34). However the nurse administering the medication had a significant effect on the O-MAE rate (p < 0.001). These results are presented in tables 10.13 to 10.17.

¹

According to the Bonferroni correction for multiple comparisons, a significance level of 0.008 was adopted.

Ward	OE	O-MAEs	O-MAE rate
Surgical	2789	76	2.72%
Medical	3278	86	2.62%

Table 10.13 O-MAE rates identified for each ward.

The difference between wards is not significant ($p = 0.87$; chi square test).

Observer	OE	O-MAEs	O-MAE rate
1	3025	91	3.01%
2	3042	71	2.33%

Table 10.14 O-MAE rates identified by each observer.

The difference between observers is not significant ($p = 0.12$; chi square test).

Nurse	OE	O-MAEs	O-MAE rate
A	81	1	1.23%
B	90	7	7.78%
C	216	9	4.17%
D	630	9	1.43%
E	393	6	1.53%
F	38	0	0.00%
G	468	17	3.63%
H	637	21	3.30%
I	523	10	1.91%
J	258	3	1.16%
K	63	1	1.59%
L	117	3	2.56%
M	66	2	3.03%
N	12	1	8.33%
O	187	2	1.07%
P	484	24	4.96%
Q	235	6	2.55%
R	14	5	35.70%
S	13	0	0.00%
T	89	2	2.25%
U	260	5	1.92%
V	315	15	4.76%
W	45	0	0.00%
X	301	6	1.99%
Y	165	2	1.21%
Z	137	5	3.65%
AA	230	0	0.00%

Table 10.15 O-MAE rates identified for each nurse.

The difference amongst nurses is significant ($p < 0.001$; chi square test).

Day	OE	O-MAEs	O-MAE rate
Monday	1104	28	2.54%
Tuesday	1001	25	2.50%
Wednesday	995	30	3.02%
Thursday	685	26	3.80%
Friday	770	14	1.82%
Saturday	695	28	4.03%
Sunday	817	11	1.20%

Table 10.16 O-MAE rates identified for each day of the week.

The difference amongst the days of the week is not significant ($p = 0.01$; chi square test¹).

Time of round	OE	O-MAEs	O-MAE rate
6 am	3026	73	2.41%
noon	764	24	3.14%
6 pm	1154	28	2.43%
10 pm	1123	37	3.29%

Table 10.17 O-MAE rates identified for each drug round time.

The difference amongst the drug round times is not significant ($p = 0.34$; chi square test).

A logistic regression confirmed that the nurse involved had a significant effect on the O-MAE rate ($p < 0.001$). Although the univariate analysis had suggested that day of week had no significant effect on O-MAEs, the results of the logistic regression analysis indicate the presence of a significant relationship ($p = 0.03$). This difference between the two analyses is most likely due to the conservative nature of the Bonferroni correction (Chi, 1998). Saturdays were associated with the highest O-MAE rates and Sundays with the lowest. The results of the logistic regression analysis also confirmed that the drug distribution system used had no effect on the O-MAE rate ($p = 0.30$). Appendix 19 presents these results in more detail.

¹

According to the Bonferroni correction for multiple comparisons, a significance level of 0.008 was adopted.

Analysis of the O-MAE rates for nurses of different grades (table 10.18) suggests that the difference amongst nurses is related to level of experience ($p = 0.004$; logistic regression analysis with polynomial contrast).

Grade	Opportunities for error observed	O-MAEs observed	O-MAE rate	95% confidence interval
Junior staff nurse	1043	44	4.2%	3.0 to 5.4%
Staff nurse	4089	101	2.5%	2.0 to 3.0%
Senior staff nurse	596	13	2.2%	1.0 to 3.4%
Sister	339	4	1.2%	0 to 2.4%
TOTAL	6067	162	2.7%	2.3 to 3.1%

Table 10.18 O-MAE rates for different grades of nurse.

The difference amongst grades is significant ($p = 0.004$; logistic regression with polynomial contrast).

Table 10.19 summarises these results according to the hypotheses tested.

Null hypothesis	Accepted/Rejected (p value)
There was no difference between the two traditional ward pharmacy system data collection periods on the medical ward in terms of their O-MAE rates.	Accepted ($p = 0.60$)*
There were no ward-related differences in O-MAE rates.	Accepted ($p = 0.38$)†
There was no difference between the O-MAE rates detected by the two observers.	Accepted ($p = 0.24$)†
There was no difference amongst nurses in terms of their O-MAE rates.	Rejected ($p = 0.0001$)†
There was no difference in terms of O-MAE rates amongst the different days of the week.	Rejected ($p = 0.03$)†
There was no difference in terms of O-MAE rates amongst the different drug round times.	Accepted ($p = 0.61$)†

Table 10.19 O-MAEs: the hypotheses tested.

* Chi square test

† Logistic regression analyses

10.6.3.2 Testing the effects of observation on MAEs

Figure 10.5 shows the O-MAE rates calculated for all those drug rounds that were the first observed round for the nurse concerned, all those that were the second observed round, and so on. This figure suggests that for the duration of the study, the O-MAE rate neither increased nor decreased with repeated observation. A logistic regression analysis with polynomial contrast confirmed that there was no statistically significant trend across successive observed rounds ($p = 0.29$).

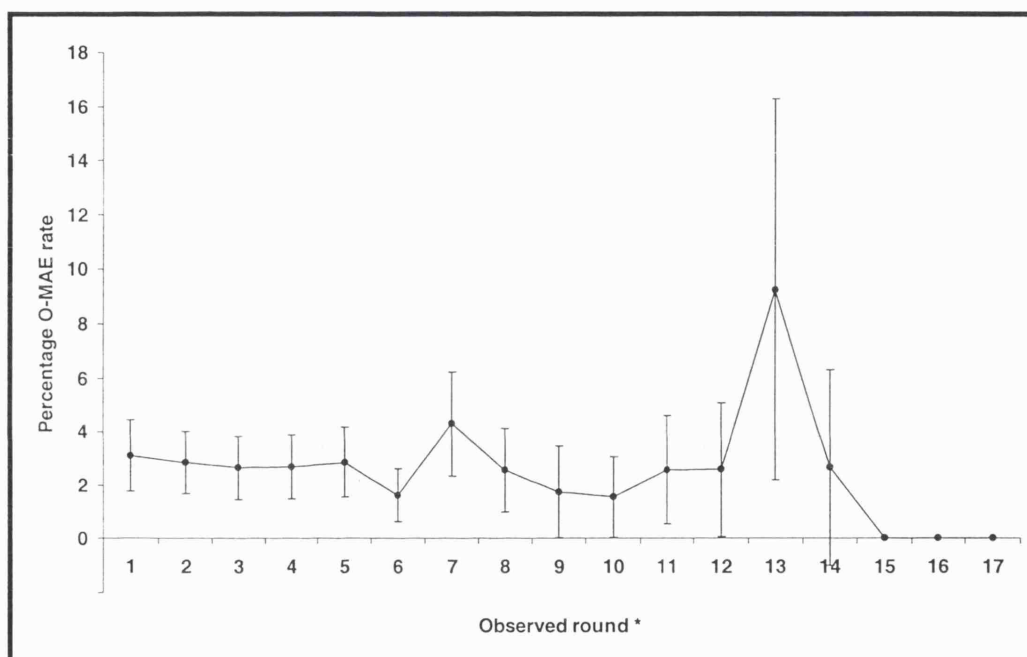


Figure 10.5 O-MAE rates for sequentially observed drug rounds; bars represent 95% confidence intervals.

* For example, '1' represents all those drug rounds that were the first observed round for the nurse concerned.

The results of the drug chart audits carried during the observed and the unobserved periods are summarised in table 10.20. The difference between the observed and unobserved periods in terms of the proportion of crosses for which a reason was documented is not statistically significant ($p = 0.77$; chi square test).

	Crosses on drug charts	Crosses with a reason given (%)
Observed periods	392	279 (71%)
Unobserved periods	228	159 (70%)

Table 10.20 Crosses on the drug chart for which a reason was documented during observed and unobserved periods on the two study wards.

A total of nineteen interventions were made (12% of all O-MAEs); these involved eight of the 27 nurses observed. Those MAEs for which interventions were made are indicated in Appendix 16. One intervention took place during the observation of the traditional ward pharmacy system on the surgical ward and seven on the medical ward; four took place during observation of the PODs system on the surgical ward and seven on the medical ward. The remaining MAEs occurred due to unavailability, were not identified until after administration or were considered very unlikely to result in patient harm.

Two additional interventions were made concerning subcutaneous doses that were not opportunities for error in the present study; both of these involved nurses with whom other interventions were also made. The first was for a dose of 5,000 units of subcutaneous heparin that the nurse prepared using 1 ml of heparin 5,000 units/ml instead of 0.2 ml of the 25,000 units/ml strength. The second concerned a dose of dalteparin 2,500 units, for which the nurse prepared 2,500 units of heparin. In each case the observer considered an intervention necessary. These interventions were therefore included in the analysis of pre and post-intervention error rates.

For those nurses with whom an intervention was made, the O-MAE rate up to and including the first intervention was 4.7%; the subsequent MAE rate was 3.4%. This difference of 1.3% is not statistically significant ($p = 0.16$; chi square test).

Although the majority of these interventions were made tactfully and discreetly, one incident towards the end of the medical ward PODs data collection phase necessitated more obvious action on the researcher's part. This involved a newly admitted patient who was given unprescribed doses of 62.5 mcg digoxin and 200mg ferrous sulphate because another patient's drug chart was at the end of his bed. The patient concerned had severe

renal impairment and cardiac arrhythmias that were being treated with amiodarone. The researcher identified the errors after the drug round when she checked the names of newly admitted patients, and was concerned that appropriate action should be taken. She therefore made the ward pharmacist and ward sister aware of the error so that the patient could be monitored appropriately. It later transpired that the patient did not take the digoxin as he did not recognise the blue-coloured tablet. However, the ward sister discussed the error with the nurse concerned and there appeared to be heightened awareness of MAEs on the ward following this event. The medical ward PODs system O-MAE rate up to and including this intervention was therefore compared to that following the event to identify any resultant change in the O-MAE rate.

A significant decrease in the O-MAE rate was identified following the intervention ($p = 0.04$; chi square test)¹. However the nurse involved (nurse C in table 10.14) did not administer any further medication following this event. If the doses administered by this nurse are excluded, the O-MAE rate before the intervention was 2.7%; this is not significantly different from the O-MAE rate of 1.0% identified subsequently ($p = 0.10$; chi square test). However, these samples may be too small to identify a difference. Even if the intervention did have an effect on the O-MAE rate, it is unlikely to have affected the trial's conclusions. The O-MAE rate identified for the medical ward PODs system was 2.4%; if the data collected after this intervention are excluded, the O-MAE rate for the PODs system on the medical ward becomes 3.1%. This difference of 0.7% is not statistically significant.

Table 10.21 summarises the results relating to the effects of intervention according to the hypotheses tested.

¹

Twenty-five O-MAEs occurred in 812 opportunities for error (3.1%) prior to the intervention and 4 in 400 opportunities for error (1.0%) afterwards.

Null hypothesis	Accepted/Rejected (p value)
There was no change in the O-MAE rate with repeated observation.	Accepted (p = 0.29) *
There was no difference between observed and unobserved periods in terms of the proportion of crosses for which a reason was documented.	Accepted (p = 0.77) †
There was no change in the O-MAE following intervention by the observer.	Accepted (p = 0.16) † ‡

Table 10.21 The effects of observation: the hypotheses tested.

* Logistic regression with polynomial contrasts.

† Chi square test.

‡ However, one major intervention may have affected the O-MAE rate, see text.

10.6.4 Comparison of the U-MAE rates identified in practice with those predicted by the model

The U-MAE rates predicted by the model and those obtained in practice are presented in table 10.22.

Ward	System	U-MAE rate predicted by the model (95% CI *)	Real world U-MAE rate (95% CI *)
Surgical	Traditional ward pharmacy	2.1% (1.9 to 2.2%)	1.6% (1.0 to 2.2%)
Surgical	PODs	1.2% (1.1 to 1.3%)	2.3% (1.5 to 3.1%)†
Medical	Traditional ward pharmacy	2.7% (2.5 to 2.8%)	1.4% (0.9 to 1.9%)†
Medical	PODs	1.8% (1.7 to 1.9%)	1.0% (0.4 to 1.6%)†

Table 10.22 U-MAE rates predicted using the model and U-MAE rates observed during the trial.

* CI: Confidence interval.

† Statistically significant difference between predicted and real world U-MAE rates (confidence intervals do not overlap).

For the medical ward, the observed U-MAE rates were significantly lower than those predicted by the model. For the surgical ward, there was no significant difference for the traditional ward pharmacy system but the observed MAE rate for the PODs system was

significantly higher than that predicted. Although not statistically significant, the real world reduction in the medical ward U-MAE rate was compatible with the model's predictions (the model predicted a reduction of 33%, a reduction of 29% was identified in the real world), but the 44% increase in U-MAEs on the surgical ward represented an opposite effect to that predicted. The model's prediction, that the introduction of the PODs system would reduce U-MAEs on both study wards, was therefore not borne out by the results of the trial.

Table 10.23 summarises these results according to the hypotheses tested.

Null hypothesis	Accepted/Rejected
Following the implementation of the PODs system, the observed U-MAE rates changed in the same direction as predicted by the model.	Rejected *
There were no differences between the U-MAE rates identified during the trial and those predicted by the model.	Rejected †

Table 10.23 Comparison of model and real world: the hypotheses tested.

* Direction of change was the same for the medical ward but different for the surgical ward.

† Confidence intervals do not overlap for three of the four study phases.

Reasons for the differences between the real world U-MAE rates and those predicted by the model will be considered in the following discussion.

10.7 Discussion

The trial of the PODs system described in this chapter represents one of the largest MAE studies carried out in a UK hospital to date. A total of 6067 opportunities for error were observed during 176 drug administration rounds. The overall MAE rates identified in each data collection period (3.4% to 5.0%) are comparable to those of other recent UK studies (Dean *et al*, 1995; Ridge *et al*, 1995; Gethins, 1996; Nixon and Dhillon, 1996; Cavell and Hughes, 1997; Ogden *et al*, 1997; Taxis, 1997); the U-MAE rates determined (1.0% to 2.3%) are also similar to those previously reported (Dean *et al*, 1995; Ridge *et*

al, 1995; Gethins, 1996; Ho *et al*, 1997; Ogden *et al*, 1997; Taxis, 1997). In each phase of the study, there were about 300 MAEs per 1000 patient days, or 0.3 MAEs per patient day. This latter figure is the same as that calculated by Ho *et al* (1997) for a care-of-the-elderly ward, although these researchers observed only three of the four drug rounds scheduled each day. Contrary to the predictions of the simulation model developed, the introduction of a PODs system did not reduce the U-MAE rate on each study ward; neither did it have any effect on the overall MAE rate or on MAE severity.

The remainder of this discussion is in four parts. First, the effects of the PODs system on MAEs will be discussed. The methods used will then be considered, before addressing the differences between the U-MAE rates predicted by the model and those that occurred in practice. Finally, some recommendations will be made for error reduction

10.7.1 The effects of the patients' own drugs system on medication administration errors

This trial represents the first study of MAEs associated with a patients' own drugs system; contrary to expectations, its introduction had no effect on the overall MAE rate. Since the power to have identified a clinically significant difference between the two systems was about 98%, it was considered very unlikely that a true difference existed between them. There were also no significant differences in the types of MAE that occurred, the stages of the drug distribution system in which they originated or in their severity.

Given the current popularity of PODs systems in UK hospitals, it is reassuring to find that MAEs did not increase. However, the PODs system was expected to reduce MAEs and the reasons why it did not are therefore of interest.

It has been suggested that because medication is selected from patients' individual medicines cabinets rather than from a crowded drug trolley, PODs systems should reduce MAEs (John, 1997; John, 1998). In the present study, the incidence of errors originating in the administration stage was very similar for both drug distribution systems (figure

10.4). However, although the numbers are too small to perform any statistical analysis, a more detailed study of the observational data suggests that there may be differences in the types of errors that occur. With the PODs system, the correct medication may be easier to locate (omissions due to nurses being unable to find medication occurred in 0.5% of all opportunities for error in the traditional system and 0.1% in the PODs system), but more errors involving the selection of the wrong number of dose units occurred. On several occasions in the PODs system, patients were administered only one tablet or capsule of their own medication when more than one should have been given in order to administer the dose prescribed. For example, one patient prescribed losartan 75mg daily had his own supply of the 50mg tablets. On two consecutive days, he was given only one tablet (50mg), instead of one and a half tablets (75mg). Such errors occurred in 0.6% of all opportunities for error in the traditional ward pharmacy system; for the PODs system this figure was 1.0%. The reasons for any increase in this type of error are unclear, although two possibilities can be suggested. First, when patients' own supplies of medication are used, there may be an assumption that only one tablet of each should be given. Second, medication dispensed by the hospital pharmacy is labelled in a standard format, whereas the labelling on patients' own medication is more varied; this may make it more difficult to identify the strength of the dose units supplied.

With respect to U-MAEs, two relevant factors were identified. First, it was found that one medication order written for a patient admitted to the surgical ward during the PODs system data collection period accounted for seven U-MAEs, representing a high proportion (23%) of the U-MAEs observed. This patient, an elderly man with peripheral vascular disease and leg ulcers, had been prescribed oral slow release tramadol by his general practitioner; this drug was therefore prescribed on his drug chart following his admission. He had not brought into hospital any of his own medication and since tramadol is not in the hospital formulary, none could be supplied. According to hospital policy, either the tramadol should have been changed an appropriate formulary analgesic or the patient's consultant should have submitted a written request for its supply. However, neither action was taken; the tramadol medication order remained on the patient's drug chart and every dose scheduled was omitted during the study period. This

event alone could have accounted for the non-significant increase in U-MAEs on the surgical ward following the introduction of the PODs system; it also illustrates how a single rare event can dramatically affect the observed MAE rate.

Second, patients' own drugs were frequently used in the traditional ward pharmacy system, in spite of this being contrary to hospital policy at the study site. Supplies of medication dispensed for a particular patient were also used to administer doses to other patients; in some cases these involved patients' own supplies of medication. These unofficial practices counteracted the flaws associated with the traditional ward pharmacy system and hence attenuated the potential benefits of a PODs system. To investigate the impact of these practices, the observers' notes were used to indicate the number of times patients' own drugs or drugs dispensed for other patients were used during the drug rounds observed; these figures are shown in Appendix 20. Where patients' own drugs were used from patients' handbags or bedside lockers, the doses were difficult to observe and in many cases were not included as opportunities for error. The MAE rate associated with these doses is therefore unknown. In some cases, patients' own drugs or drugs dispensed for other patients were used even though hospital supplies were available for the patient concerned; in other cases no other supply of the medication was available and omission errors would otherwise have occurred. It can be estimated that at least another 32 U-MAEs (15 on the surgical ward and 17 on the medical ward) would have occurred during the traditional ward pharmacy system data collection periods had these sources of medication not been used. In contrast, during the PODs system data collection periods, there were only two cases observed in which drugs dispensed for one patient were administered to another.

Had neither of these factors been present, the U-MAE rates observed would have been those shown in table 10.24. According to these data, the introduction of a PODs system would have reduced the U-MAE rate by a statistically significant amount on the medical ward ($p = 0.01$; chi square test) and by a non-significant amount on the surgical ward ($p = 0.20$). If the adjusted data for the two wards are combined, the difference between the two systems is also statistically significant ($p = 0.01$).

Ward	System	Adjusted figures		
		OE*	U-MAEs	U-MAE rate
Surgical	Traditional ward pharmacy	1510	39	2.6%
Surgical	PODs	1279	23	1.8%
Medical	Traditional ward pharmacy	2066	46	2.2%
Medical	PODs	1212	12	1.0%

Table 10.24 Adjusted U-MAE rates (see text).

* OE: Opportunities for error

The use of patients' own drugs is contrary to hospital policy for the traditional ward pharmacy system, but reduces the incidence of U-MAEs. Such behaviour, in which procedures are disregarded but the outcome is appropriate, has been termed 'correct violation' (Reason, 1997). However, there are several reasons why hospital policy does not allow the use of patients' own medication in the traditional ward pharmacy system. There are no procedures for obtaining patient consent for the use of what is their own property and there is nowhere appropriate for patients' own medication to be stored. If patients' own medication is stored in the drug trolley it may be lost, returned to pharmacy or used for other patients; if it is kept at patients' bedsides its storage is not secure. There are also no procedures for ensuring that patients' own medication is in good condition and appropriate for use. The introduction of a formal PODs system therefore addresses these issues and ensures that patients' own medication is stored and used appropriately.

One of the reasons for the extensive use of patients' own medication on the medical ward was that some patients administered their own medication, a practice which is also contrary to hospital policy. However, discussion with nursing staff revealed that many renal transplant patients prefer to administer their own medication, which often involves complex immunosuppression therapy. In particular, these patients wished to take their medication at the same times as they did at home, rather than at the times of the nurses' drug rounds. Given that adherence to prescribed immunosuppressant regimes is essential for this patient group, encouraging patients to be responsible for their own medication is particularly important. However, it is of concern is that these patients stored their medication in their bedside cupboards, which cannot be locked. The issue of self-

administration therefore needs to be addressed in the study hospital. For example, in wards using PODs systems, suitable patients could be given keys to their medicine cabinets and given responsibility for self administration, provided appropriate procedures were in place (Semple *et al*, 1995).

In summary, the potential for a PODs system to reduce MAEs was not borne out in practice on the wards studied. However, neither did MAEs increase in frequency or in severity. Since PODs systems have other potential advantages, their growing use in UK hospitals should be supported and further evaluated.

10.7.2 Evaluation of the methodology

10.7.2.1 Validity of the data collection methods used

An observation-based method was selected with which to identify MAEs; this was considered to have higher validity than any of the alternatives. Data obtained from patients' administration records were also used to supplement the observational data, to aid in the identification of omission errors. This approach has previously been criticised for compromising the accuracy of the results obtained (Allan and Barker, 1990; Gibson, 1996). However, the results of the pilot study described in section 9.3.4 provide some information about its validity. During the pilot study, it was found that where the relevant section of the drug chart was signed, the dose had actually been given in 99.8% of cases. It was therefore considered reasonable to assume that doses omitted during a drug round but subsequently signed for had actually been given. However, where the drug chart was left blank during the pilot study, the dose had actually been given in 30% of cases. The use of this method may therefore overestimate, rather than underestimate, the U-MAE rate. However, without using this approach, an observer would have had to be present on the ward twenty-four hours a day to be certain that doses were never given; alternatively, omission errors would have had to be excluded from the study. The use of patients' administration records in parallel with observation was therefore the only practical approach.

Other issues that must be considered are potential confounding factors and potential sources of bias.

10.7.2.2 Potential confounding factors

Since the trial was not randomised, it was essential that potential confounding factors were identified and controlled for. As discussed in section 9.6, a suitable experimental design was selected to control for both ward-related factors and time-related factors. Ward-related factors included potential differences in staff, patients and systems of work; however, in the present study there were no significant differences in MAEs between the two study wards.

Time-related confounding factors included changes in hospital policy, changes in staffing levels, changes in bed occupancy and changes in the level of pharmacy services provided. It was assumed that such factors would be relevant on a hospital-wide basis and therefore comparable on each of the two study wards. Repeated observation of the traditional ward pharmacy system on the medical ward suggested that there were no time-related changes in MAE rates between the end of January and the end of March 1998. However the sample size in each of these data collection periods was smaller than anticipated. Given the sample sizes achieved, the power to have detected a clinically significant difference between the two medical ward data collection periods in terms of the overall MAE rate was only 0.62. Ideally, a repeat evaluation of the PODs system would also have been carried out in June on the surgical ward, to identify any time-related changes in MAE rates between March and June. Unfortunately, time constraints precluded additional data collection and since the MAE rates were similar throughout the trial, it was assumed that no time-related differences in MAEs occurred.

The effects on MAEs of the nurse administering the medication, the day of the week and the time of day were also explored, to identify any other sources of variation within the results obtained. It was found that day of week and time of day had significant effects on the U-MAE rate; U-MAEs were most likely to occur on Fridays and most likely to occur

during the noon drug round. However, no reasons for these findings could be identified. One factor affecting the incidence of O-MAEs was the day of the week; O-MAEs occurred most often on Saturdays and least often on Sundays. Again, no corresponding reason could be identified. This is only the second UK MAE study to have included observations at weekends; in the first such study, Ho *et al* (1997) found that MAE rates were lower on weekend days than during weekdays. However this study took place on a care of the elderly ward, on which the majority of admissions, discharges and medication order writing took place between Monday and Friday; this ward is unlikely to be comparable to those that were included in the present study.

A second factor that affected the O-MAE rate was the nurse administering the medication. This effect was found to be related to level of experience, with the incidence of O-MAEs decreasing with increasing nursing experience. This contrasts with the findings of a previous study, in which no significant differences in U-MAE, O-MAE or total MAE rates were identified for different grades of nurse (Ridge, 1998). The reason for the difference between the two studies is unclear, although it may be related to the different categories of nursing staff used by the two researchers.

Since observations were made for the two drug distribution systems on the same days of the week, at the same times of day and with the same nurses, these sources of variation in MAE rates should not have affected the trial's results. However, these findings have important implications for the design of future studies; these will be discussed in more detail in Chapter Eleven.

10.7.2.3 Potential sources of bias

In any experiment involving people, there are potential sources of bias. Subject bias can arise when the people being studied are aware that the research is taking place; observer bias can also occur if the observer is not blinded to the alternatives being evaluated (Robson, 1993).

Whenever observation-based methods are discussed, the most commonly cited objection

is that the observation itself must affect nurses' practice and hence the MAE rate. Logically, however, observation would not be expected to affect U-MAEs, or O-MAEs that occur due to lack of knowledge. Only O-MAEs that occur due to carelessness or lack of concentration would be likely to be affected. In the present study, every effort was made to minimise the effects of the observation on the people observed; in addition, two different approaches were used to identify any remaining effects. It was found that there was no change in the O-MAE rate with repeated observation, and no difference between observed and unobserved periods in the proportion of omitted doses for which a reason was documented. These results, together with those of previous studies (Barker *et al*, 1966; Dean, 1993; Ridge, 1998), suggest that concerns regarding the effect of the observer on MAEs are unfounded. An additional consideration in UK studies is that the observer's interventions could affect the incidence of MAEs. In the present study, it was decided to intervene only where it was possible to prevent a serious error from occurring. Interventions were therefore made in only 19 cases (12% of all O-MAEs) and overall, these interventions had no significant effect on the O-MAE rate observed. However, one necessarily less subtle intervention, resulting in increased awareness of MAEs on the study ward concerned, may have reduced the incidence of O-MAEs. This intervention occurred towards the end of the study; the exclusion of doses administered after this event from the O-MAE rate calculated does not affect the study's conclusions.

Observer bias in MAE research has not previously been considered. In common with all comparative studies of MAEs, the observers in the present study were not blinded to the drug distribution system being used. It is therefore possible that the observers' expectations or hopes regarding the new system could have affected the results obtained. However blinding would have been impossible to achieve, and since MAE rates were not calculated until all data collection had been completed, observer bias was considered to be unlikely.

A related issue is that of observer error. In an early MAE study, Barker *et al* (1966) attempted to assess inter-observer reliability by asking two researchers to observe the same nurse. However, the two observers found it difficult to position themselves so that

both could see the medication administered, and it was concluded that the assessment of inter-observer reliability was impractical. As a result, little is known about observer reliability in this context. In the present study, the two observers both collected data on each ward; analysis of the MAE rates detected suggests that there was no difference between the two observers, a finding which is reassuring with respect to their reliability. However, even using two observers, the data collection was found to be very labour-intensive and it is possible that observer fatigue could have affected the results obtained. The overall MAE rates were therefore analysed according to the number of drug rounds observed by each observer during each data collection period; there was no change in the MAE rate with increasing observation ($p = 0.65$; logistic regression analysis with polynomial contrast). This finding suggests that there was no effect of observer fatigue for the duration of the data collection periods used. However, given the labour-intensive nature of the observation, it is suggested that data collection periods of more than seven consecutive days require more than two observers.

10.7.3 Comparison of the U-MAE rates identified in practice with those predicted by the model

The results obtained from the simulation model suggested that the introduction of a PODs system would reduce U-MAEs on both study wards. However, during the trial, the U-MAE rate showed a slight increase on the surgical ward. There were also small but significant differences between the percentage U-MAE rates predicted and those identified in practice. Potential reasons for these findings were therefore explored.

A key assumption made when modelling the PODs system was that about 50% of those patients who were taking medication prior to their admission would bring supplies of their medication into hospital. Had this percentage been different during the trial, the predicted benefits of the PODs system would have been expected to be different to those obtained in practice. However, during the PODs system data collection periods, 58% of the observed patients on the surgical ward and 54% on the medical ward who had been taking medication prior to their admission brought supplies into hospital. The assumption

made during model construction was therefore considered appropriate and the U-MAE rates identified during the trial should have been comparable to those predicted by the model.

Further examination of the model's assumptions led to the identification of four factors likely to have contributed to the differences between the predicted and real world U-MAE rates. First, as previously discussed, patients' own medication was frequently used in the traditional ward pharmacy system, and supplies of medication dispensed for a particular patient were used to administer medication to other patients. Neither of these practices were taken into account during model construction.

Second, although it had been assumed during model construction that stock and previously dispensed drugs would always be available, many of the U-MAEs identified occurred due to the depletion of ward stock drugs or previously dispensed non-stock drugs (table 10.2). In particular, previously dispensed medication frequently ran out on the surgical ward in each phase of the trial. There was no policy in the study hospital regarding the quantity of non-stock medication that should be supplied; as a result five-day or seven-day supplies were usually made which quickly became exhausted. It was also noted that more than one patient was sometimes prescribed the same medication but only one supply made; a five-day supply could therefore become exhausted within three days. Finally, the surgical ward pharmacist apparently made new supplies only when nurses requested them. In many cases nursing staff waited until the last dose had been used before requesting a further supply; in other cases no request for a repeat supply was made. Doses were therefore omitted while the medication was being re-dispensed.

Third, it was noted that in both drug distribution systems, doses that were unavailable during the drug round for which they were scheduled were sometimes given later once the medication concerned had been supplied. It had been assumed during model construction that the effect of this practice was negligible. However the observers' notes suggested that particularly on the medical ward, this was not the case (appendix 21). In total, 26 doses were given later following their subsequent supply; these represent 26 U-MAEs that

would have otherwise occurred. It can be estimated that on the surgical ward, about 8% of doses that were unavailable during the round for which they were scheduled were given later; the corresponding figure for the medical ward is 34%. There is no hospital policy concerning whether such doses should be given later or omitted and nurses were often unsure of the most appropriate action to take.

Finally, as discussed previously, one non-formulary medication order written for a patient admitted to the surgical ward during the PODs data collection period accounted for 7 of the 30 U-MAEs observed; however the unavailability of non-formulary medication was not considered in the model.

If these four factors had not existed, the real world U-MAE rates would have been those shown in table 10.25. These U-MAE rates are comparable to those predicted by the model and suggest that the introduction of the PODs system would have decreased the incidence of U-MAEs as predicted.

Ward	System	U-MAE rate predicted by the model (95% CI*)	Adjusted real- world U-MAE rate (95% CI)
Surgical	Traditional ward pharmacy	2.1% (1.9 to 2.2%)	1.8% (1.1 to 2.5%)
Surgical	PODs	1.2% (1.1 to 1.3%)	0.9% (0.4 to 1.4%)
Medical	Traditional ward pharmacy	2.7% (2.5 to 2.8%)	2.4% (1.7 to 3.1%)
Medical	PODs	1.8% (1.7 to 1.9%)	2.1% (1.3 to 2.9%)

Table 10.25 U-MAE rates predicted by the model and the U-MAE rates that would have occurred in practice had the four factors cited in the text not existed.

* CI: Confidence interval.

Comparing the U-MAE rates predicted by the model with those identified during the trial has therefore provided useful information. This process has highlighted the potential effect of single events, such as the continued non-supply of a non-formulary drug, on the observed MAE rate. Key differences between recommended practice and actual practice have also been identified. Discussions with pharmacy staff at the study hospital suggest that they were unaware of these issues; appropriate action can now be taken and the

reasons why procedures are not followed can be explored. The procedures may be inappropriate, staff may be unaware of them, or they may need reinforcing. Further research is needed to explore these issues in more detail.

10.7.4 Recommendations for reducing medication administration errors

There are a number of areas where action could be taken to reduce MAEs in both the traditional ward pharmacy system and the PODs system. With respect to U-MAEs, the results of this study suggest that a key issue in the study hospital is the timely repeat supply of previously dispensed medication. To reduce U-MAEs, consideration should be given to making larger supplies of non-stock medication, and in accordance with hospital guidelines, repeat supplies should be made before the last dose of the previous supply has been administered. Appropriate action should also be taken when non-formulary drugs are prescribed.

Other recommendations can be made regarding the prevention of O-MAEs. In the present study, ambiguous medication orders were judged to have contributed to 22% of the O-MAEs identified; this is the same percentage as that identified in a previous study (Dean *et al*, 1995). An example identified in the present study was the prescription of isosorbide mononitrate as 'ISMN' which was interpreted as 'ISTIN'¹ and a dose of amlodipine given. Such findings suggest that improvements in medication order writing (or the printing of administration instructions) could have a beneficial effect on medication administration errors.

In common with previous studies (Dean *et al*, 1995; Cavell and Hughes, 1997), other errors occurred due to the selection of medication of the incorrect pharmaceutical form. For example, a patient prescribed nifedipine LA 30mg ² once daily was given instead

¹ Istin is the brand name for amlodipine tablets.

² Nifedipine LA is a long acting formulation designed to be given once daily.

three tablets of nifedipine SR 10mg³. It was the observers' impression that many nurses did not appreciate the differences between such modified-release preparations, highlighting the existence of specific training needs.

Finally, although 59% of the omission errors resulted from the unavailability of the medication concerned, the remaining 41% occurred because nurses did not notice that doses were due or could not find medication on the ward. The reasons why nurses did not notice that doses were due are unclear, although often the drug charts were untidy and difficult to interpret. In many cases, drugs could not be found because they were prescribed by generic name and supplied by brand name, or vice versa. Ward pharmacists should be able to alleviate some of these problems by ensuring that nurses know how to use reference sources such as the British National Formulary and by annotating drug charts to aid selection of the correct medication.

The wider implications of these findings, together with some suggestions for future work, will be considered in the next section of this thesis.

3

Nifedipine SR is a slow release formulation designed to be given twice daily; its duration of action is shorter than that of the LA preparation.

Part E

Discussion and conclusions

‘The outcome of any serious research can only be
to make two questions grow where one question grew before.’

Thorstein Veblen (1908)

University of California Chronicle

‘Evolution of the Scientific Point of View’.

Chapter Eleven: Discussion and conclusions

At the beginning of this thesis, existing approaches to the study of medication administration errors (MAEs) were discussed and a number of limitations highlighted. It was concluded that an alternative approach to the study of MAEs was required and mathematical modelling was proposed as a potential solution. It was also decided that methods for assessing MAE severity should be explored. A discrete-event simulation model of the hospital drug distribution system was constructed, this was used to investigate the effects of changes to the system on unavailability-related MAEs (U-MAEs). A new method for assessing the severity of MAEs was also developed. This method was shown to be reliable and valid; it is also practical for use in observation-based studies. A patients' own drugs (PODs) system, predicted by the model to reduce U-MAEs by a clinically meaningful amount, was then implemented on two study wards. An observation-based method was used to identify MAEs both before and after its introduction. The U-MAE rates identified were compared with those predicted by the model; other types of medication administration error (O-MAEs) were also studied and MAE severity evaluated. It was found that contrary to the model's predictions, the introduction of a PODs system did not reduce U-MAEs on both study wards. The PODs system also had no effect on the overall incidence of MAEs or on the severity of the MAEs that occurred.

In this discussion, some of the wider implications of these findings will be considered. First, the use of mathematical modelling to study MAEs will be discussed and some suggestions made for further work. The assessment of MAE severity will also be addressed, before discussing the implications of the study's results for future MAE research. Some potential limitations to the study will then be considered. The chapter ends by summarising the contribution made to existing knowledge and the study's main conclusions.

11.1 Mathematical modelling of the hospital drug distribution system

One of the aims of this thesis was to explore the use of mathematical modelling to investigate the effects on U-MAEs of changing the hospital drug distribution system. After considering the characteristics of this system, a discrete-event simulation model was constructed. A key question is therefore whether this approach was found to be useful.

The simulation results suggest that different changes to the drug distribution system have different potential benefits; the relative benefits of each were similar for the two wards studied. The most significant reductions in U-MAEs could be obtained by introducing relatively simple changes to pharmacy services. Without using simulation, it would have been reasonable to suggest that each of the changes investigated would reduce U-MAEs, but it would have been impossible to identify those likely to offer the most benefit. The results also suggest that the mean length of stay of the patient group could have a significant effect on U-MAEs. Such findings would be useful for the planning of pharmacy services and MAE research, and for the design of hospital drug distribution systems.

However, although the model predicted that the PODs system would dramatically reduce U-MAE on each study ward, the trial's results suggested otherwise; during the trial, there was a 29% reduction in the U-MAE rate on the medical ward but a 44% increase on the surgical ward. Reasons for this finding were explored and four contributing factors identified. Each of these relates to assumptions made during the modelling process about the operation of the hospital drug distribution system, and highlights its complexity.

Three of the four factors relate to hospital policy not being followed; since the model was based on hospital policy, its predictions were at variance with what was observed. This raises an important issue, which is whether a model should represent the real system as it ought to operate, or how it actually operates in practice. Modelling the system as it should operate can illustrate the potential effects of a change to that system; modelling the system as it operates in practice demonstrates the impact likely in reality. This distinction corresponds to the difference between the efficacy and the effectiveness of a medical

intervention. An efficacious treatment is one that has been shown to be beneficial under the controlled conditions of a clinical trial where people fully comply with recommendations and treatments, while an effective treatment is one that works in routine practice (Drummond *et al*, 1987). In the present study, the model constructed was based on hospital procedures; it was implicitly assumed that this would reflect how the system operated in practice. However, the observational study highlighted some important differences between hospital procedures and routine practice. These findings have useful implications for future work. With respect to the model developed in the present study, several modifications should be made if it is to more closely represent the drug distribution system as it operates in reality. A more comprehensive model should therefore include the use of patients' own medication in the traditional ward pharmacy system and the exhaustion of dispensed supplies of non-stock medication. The effects of prescribing non-formulary medication could be taken into account, as should the late administration of previously unavailable medication. Such modifications would allow the model to be run using different sets of assumptions regarding whether or not hospital procedures are followed, and should increase its validity.

Some advantages and disadvantages of using simulation modelling can be identified. First, a key advantage of simulation is that large sample sizes can easily be achieved. The observation of drug rounds is tiring and labour intensive, and although the numbers of opportunities for error observed during the present study were large in comparison to those observed in previous studies, the samples remain very small in comparison to those achieved using the simulation model.

Second, simulation allows different systems to be compared under identical conditions, with identical groups of simulated patients. In contrast, during the observation-based trial, the admission of one patient who was prescribed a non-formulary drug had a dramatic effect on the U-MAE rate identified for the surgical ward PODS system. It would have been impossible to match the patients admitted during each phase of the trial and such anomalies were therefore impossible to prevent. The only way this problem could have been avoided would have been to conduct a much larger trial, but the

resources required made this impractical.

Third, simulation allowed many different changes to be investigated. In the present simulation study, a whole series of changes were explored and the relative benefits of each identified. It would have been impractical to evaluate each of these using observational methods.

Finally, it was found that the data collection and modelling processes carried out led to increased understanding of the hospital drug distribution system. Exploring reasons for the differences between the predicted and real world U-MAE rates also enhanced this process, prompting questions about some of the assumptions made regarding how the system operates.

A disadvantage associated with mathematical modelling is that model validity can be difficult to assess. In the present study, two hospital pharmacists assessed the face validity of the assumptions made during model construction and all were considered appropriate, while the observation-based trial revealed several to be invalid. However, the modelling process should always be iterative (Law and Kelton, 1991; Pidd, 1998) and the findings of the present study can be used to increase the model's validity in this respect.

A second disadvantage in relation to the present study was that the data collection required to provide values for the model's input variables was relatively labour-intensive. In particular, determination of the times of medication order writing required the researcher to visit each study ward every two hours for a fourteen-day period. Since the sensitivity analysis suggested that patterns of medication order writing could have a significant impact on U-MAE rates, similar data would be needed for any ward modelled. However, in the future, increased use of computerised prescribing will mean that prescribing times data will be readily available from many hospital computer systems (Slee and Farrar, 1998), obviating the need for manual data collection. Furthermore, the sensitivity analysis carried out in the present study indicated those input variables to

which the model's output is most sensitive; estimated values could be used for the less sensitive input variables in future work.

It is clear that all assessment methods have advantages and disadvantages, and both modelling and observational studies have a potentially valuable role. Modelling can be used to increase understanding of a system and explore how it may respond to change, while observation permits the more detailed study of its behaviour, albeit based on much smaller samples.

With regards to future work, it is suggested that the model constructed in the present study is further refined so that it more closely represents the drug distribution system as it operates in practice. This model could then be used to investigate many different changes to the hospital drug distribution system on a more extensive range of simulated wards. Given suitable training, hospital pharmacists could also use the model to study the effects of implementing different changes in their own hospitals, using hospital-specific data.

A similar simulation model could be used to assess the clinical aspects of different drug distribution systems. For example, one study in a hospital operating a typical clinical pharmacy service suggests that the mean lag time between medication order writing and a pharmacist's clinical intervention is 39 hours for medication orders written from Mondays to Fridays, 73 hours for those written on Saturdays and 54 hours for Sundays (Farrar *et al*, 1998). Since many interventions are potentially life-saving (Batty and Dhillon, 1997), these findings suggest that the existing model of service provision is inadequate. A suitable model could be used to explore the effects on these lag times of different changes to clinical pharmacy services.

Another potential research area is the modelling of O-MAEs. One problem is that little is known about the causes of O-MAEs; it would therefore be difficult to predict the effects on O-MAEs of changing the system. In the present study, the drug distribution system was modelled as a complex series of queuing processes; if a drug was not available on the ward when it was needed then it was assumed that a U-MAE would occur. However,

there is no corresponding way to determine when an O-MAE will occur and it is likely that many different psychological processes are involved (Senders and Moray, 1991). A different approach would therefore be needed. One possible solution would be to use methods based on human reliability analysis (Reason, 1990); this approach is used in the nuclear power industry and involves estimating the probability of an error occurring during the execution of different tasks. The failure rates of different systems could then be estimated according to the tasks involved.

It was concluded that simulation modelling is a potentially useful approach to the study of U-MAEs associated with different drug distribution systems, although the model developed needs some further refinement. Such a model could then be used to explore the effects of many different changes to the drug distribution system and to identify those that should be subjected to further testing in the real world situation.

11.2 Assessing the severity of MAEs

The second aim of this research was to explore methods for assessing MAE severity. Although techniques for assessing the severity of MAEs are described in the existing literature, none meet the criteria of validity, reliability and practicality for use in observation-based studies. A new method was therefore developed; this is the first valid and reliable method that can be used in observation-based MAE research. It is also quick and simple to use, requiring only about half a minute per MAE case per judge; it is thus suitable for use in both research and the routine assessment of MAEs reported in the hospital setting. This method could be used in future MAE research and since it has been shown to be reliable, error severities could be compared amongst different studies. Further work should explore the international applicability of the method developed, so that it can also be used in comparative studies of MAEs in different countries (Dean *et al*, 1995; Taxis, 1997).

As well as the study of MAEs, there are many other situations in which scoring methods are urgently needed; these include studies of doctors' prescribing errors (Lesar *et al*,

1990) and pharmacists' clinical interventions (Cousins *et al*, 1997). The approach adopted in the present study, using generalisability theory to address reliability and cases with known outcomes to assess validity, could be used to design similar methods for assessing the significance of these events.

11.3 Studying hospital medication administration errors

Methods for studying MAEs were first developed in the 1960's (Barker and McConnell, 1962; Vere, 1965; Hill and Wigmore, 1967). However, many of the methodological questions raised at that time have remained unaddressed. As well as exploring the use of mathematical modelling to study U-MAEs, the present study provides some answers to key issues in MAE research: study design, data collection methods, the definition and classification of MAEs, and the calculation of error rates.

Study design is a fundamental concern in all experimental research. With respect to studying MAEs associated with different drug distribution systems, there are factors other than the drug distribution system that could affect MAEs and must therefore be taken into account. Few previous studies have been large enough to allow any such factors to be identified, however the results of the present study provide some preliminary insights. The only variables found to affect the U-MAE rate were time of day and day of week, there was no significant effect of nurse, observer or ward. In contrast, the nurse administering the medication had a major effect on O-MAE rates, day of week had some effect and ward, observer and time of day had none. These findings suggest that when studying U-MAEs, experimental groups should be equivalent in terms of the days and times studied, and when studying O-MAEs, the potential effect of the nurse must also be taken into account. Ideally, the same nurses should be studied using each drug distribution system, or if this is not possible, nurses could be randomly assigned to the different systems. For example, it may be feasible to introduce a new system on only half of a study ward, and randomise nurses into two teams, so that each team would use one system. The findings of the present study also emphasise the importance of achieving sample sizes that are as large as possible. The admission of one patient prescribed a non-

formulary drug accounted for 23% of the U-MAEs identified in one phase of the trial, highlighting how even in a comparatively large study, single rare events can have a substantial effect on the results obtained.

There has also been considerable debate over the methods used to identify MAEs. Observation is generally considered to be the most reliable method (Allan and Barker, 1990), however concerns are often raised about the potential for the observation itself to affect nurses' behaviour and hence the MAE rate. As discussed in Chapter Ten, the results of the present study suggest that these concerns are unfounded, even if the observer tactfully intervenes to prevent errors from occurring.

However, other findings of the present study raise questions about the supremacy of observation for the study of MAEs. This is the first time MAEs identified in an observational study have been assessed in terms of severity using a validated method, and the results suggest that none were likely to result in serious harm. Although this finding is reassuring, it is known that serious MAEs do occur in UK hospitals (Ferner and Whittington, 1994; Cousins and Upton, 1995). It is possible that the more severe errors occur in areas such as intensive care units, where more doses are administered, more powerful drugs are given and patients' clinical status is more critical. However, only two observation-based studies of MAEs have been carried out in critical care areas and neither of these considered the severity of the errors identified (Tisdale, 1986; Schneider *et al*, 1998). It is also possible that serious errors are sufficiently rare that methods other than observation are needed to identify and study them. In this case, a potential option would be to use the critical incident technique, which involves the in-depth analysis of large numbers of individual errors to identify common causal factors (Flanagan, 1954; Vincent and Bark, 1995). This method cannot be used to study the incidence of errors, but it could be used to glean information about the factors involved. The critical incident technique has previously been applied to accidents in anaesthesia (Cooper *et al*, 1978; Cooper *et al*, 1984; Currie *et al*, 1993; Webb *et al*, 1993), intensive care (Wright *et al*, 1991) and transfusion medicine (Kaplan *et al*, 1998), but there have been no recent reports of its application to MAEs.

Even where the same data collection methods have been used, the results of published MAE studies can be difficult to interpret due to wide variations in the definitions used. In the present study, the definition and classification of MAEs were therefore considered in detail. Many of the sources of variability amongst previous studies were identified and two comprehensive sets of exhaustive and mutually exclusive categories developed. One of these considers the type of discrepancy between the medication prescribed and that administered; the second is based on the stage of the drug distribution system in which the error originated. These classification systems are more rigorous than those used previously, some of which allow one error to be counted twice (Barker and Allan, 1995).

A related issue is the denominator used to calculate the MAE rate. In the present study, MAE rates were calculated using as a denominator the number of opportunities for error (OE); this was to aid comparison with previous observation-based studies, the majority of which have used this approach. However, some quantitative studies using other data collection methods calculate error rates per patient admission (Raju *et al*, 1989; Brennan *et al*, 1991; Wilson *et al*, 1995); it is impossible to compare the results of such studies with those of studies using OE. One solution may be to calculate error rates per patient day (or per 1000 patient days) as most hospitals record numbers of occupied bed days. Table 11.1 shows the results of the present study expressed as errors per 1000 patient days.

Ward	System	MAEs per 1000 patient days		
		U-MAEs	O-MAEs	All MAEs
Surgical	Traditional ward pharmacy	130	227	357
Surgical	PODs	156	177	333
Medical	Traditional ward pharmacy	95	186	281
Medical	PODs	77	186	263

Table 11.1 Medication administration errors (MAEs) per 1000 patient days.

Surprisingly, these figures lead to different conclusions to those obtained when error rates were calculated according to the established method of OE (table 10.1). When analysed

according to OE, the O-MAE rate showed a non-significant decrease on the medical ward following the introduction of the PODs system; the overall MAE rate showed a non-significant increase on the surgical ward. In contrast, table 11.1 suggests that the O-MAE rate remained the same on the medical ward and the overall MAE rate decreased on the surgical ward. The most logical explanation for these anomalies is that OE per patient day is not a constant. In the present case, it is likely that the two calculation methods give different results because any differences in MAE rates between the two systems were very minor; had there been large differences between the two drug distribution systems it is unlikely that the two methods would have given different conclusions. However, these findings emphasise the importance of specifying how MAE rates are calculated and highlight the difficulties of communicating risks. A related situation is encountered when comparing different modes of transport. For example, if deaths per distance travelled are considered, it can be concluded that flying is much safer than driving. However, if the numbers of deaths per hour of travelling time are calculated, flying appears more dangerous than driving (The Royal Society, 1992). Again, these differences arise because the distance travelled per hour is not the same for the different types of transport. With respect to future observation-based MAE research, it is suggested that error rates are calculated according to OE as is current practice, and that error rates per 1000 patient days are also quoted to aid comparison with other studies. However, researchers should be aware that the conclusions drawn using errors per 1000 patient days will not necessarily be the same as those obtained using OE.

There are therefore several issues that should be considered in future studies of MAEs. Data collection methods should be selected according to the objectives of the research; observation is the most appropriate method for quantifying the incidence of common MAEs, while other methods should be explored for the study of more serious errors. MAE definitions should be carefully considered and in quantitative studies, the number of errors per 1000 patient days should be quoted in addition to error rates calculated using OE.

Future work should also consider the costs associated with MAEs. Only a small number

of previous studies have attempted to explore this issue. Bates *et al* (1997) concluded that each preventable adverse drug event (medication error) was associated with an additional cost of more than \$5000, excluding legal costs. However, these results include only those medication errors that resulted in identifiable harm and do not distinguish between prescribing errors and administration errors. Schneider *et al* (1995) assessed the costs associated with medication errors and adverse drug reactions described on hospital incident reports; careful reading of the paper suggests that each event costs, on average, an extra \$783. However, the data for medication errors and adverse drug reactions are presented together and it is not possible to calculate a figure that applies to medication errors alone. Further studies are needed to examine the costs of MAEs and more importantly, how much it costs to prevent them. In theory, it should be possible to prevent all errors if enough resources are available. In practice, resources are limited and must be used in the most effective way. Future work should therefore consider how appropriate economic analyses could be carried out, to identify the most cost-effective approaches to error reduction.

Finally, further work should explore the relevance of what have been called ‘latent failures’. Reason (1990; 1997), in his work on human error, suggests that errors can be attributed to both ‘active failures’ and ‘latent failures’. Active failures involve staff at the ‘sharp end’ of a system; latent failures are errors related to issues such as management decisions, organisational culture and staff training. Berwick (1998), in a similar vein, distinguishes between the ‘system of work’ and the ‘system of management of work’ or ‘meta-system’; he emphasises that to increase safety, the meta-system must also be taken into account. In common with previous MAE research, the present study focused on the system of work; further work should explore the meta-system issues involved.

11.4 Study limitations

There are several potential limitations to the study as a whole that must be considered. First, only one type of mathematical model, a discrete-event simulation model, was investigated. Although this was considered the most appropriate approach for the present

study, there are many other types of mathematical model (Law and Kelton, 1991; Taha, 1995) and many other approaches that could have been explored.

Second, only regularly prescribed oral, nasal, ocular, inhaled and aural doses were included throughout the present study. Parenteral, controlled, rectal, topical, 'once only' and 'when required' doses were excluded from both the data used in the model and that collected during the trial. To gain some insight into the relevance of these exclusions, the observers' notes were used to identify the 'when required' and 'once only' doses given during the observed drug rounds. It was found that 300 such doses were administered, representing about 5% of all doses given during scheduled drug rounds. The numbers of 'when required' and 'once only' doses given between drug rounds are unknown but are not thought to be significant. Analysis of data collected during the fourteen-day prescribing times study (section 4.5) suggests that on the surgical ward, about 25% of all regularly scheduled medication orders are for parenteral, rectal, topical or controlled drugs. The corresponding figure for the medical ward is 11%. It can therefore be estimated that about 70% of all doses were included on the surgical ward and 85% on the medical ward. The error rates associated with the excluded doses are unknown, however the PODs system did not affect the supply or administration of parenteral, topical, rectal or controlled drugs and their exclusion is unlikely to have affected the trial's conclusions.

A third issue is that of generalisability; this was raised as a potential problem at the beginning of this thesis and the present study is no exception. There are several levels on which generalisability can be considered. Starting at the highest level, this study took place in a UK NHS hospital; it is unlikely that the findings will apply directly to different countries or different health care systems. The next level is between different hospitals. It is difficult to assess how typical the study hospital is, as there are few data available with which to make comparisons. A survey carried out in 1992 found that 74% of UK hospital pharmacies opened on Saturdays and public holidays, while 90% remained closed on Sundays. Only 27% were in teaching hospitals and only 9% had a resident on-call pharmacist (Cotter *et al*, 1994). The study hospital is a teaching hospital, operates a residency service and opens on both Saturday and Sunday mornings; as such it is not

typical of UK hospitals as a whole. However, the drug distribution system used in the study hospital was considered very similar to those used in hospitals throughout the UK.

The next level of generalisation is between hospital wards. Ward characteristics are as difficult to quantify as those of hospitals. The model's results suggest that mean length of stay and times of prescription writing may be important factors with respect to U-MAE rates; these parameters are likely to show wide variation amongst different wards.

Although prescribing times have been recorded in previous studies (Bottomley, 1993; Hartland, 1996; Ho *et al*, 1997), different inclusion and exclusion criteria mean that it is almost impossible to compare the results obtained. The extent to which the findings of the present study can be generalised to different wards is therefore unknown. Finally, individual pharmacists, nurses and doctors must also be considered. A key issue in the present study was the differences between standard hospital policy and routine practice; it is not known whether this is typical of other UK hospitals. However, Haslam (1987) in an observational study of drug administration practice, found many situations in which hospital procedures were not followed. It was therefore considered unlikely that the hospital used in the present study was particularly unusual in this respect.

11.5 Conclusions

This thesis has made a number of contributions to existing knowledge. It describes the first ever application of simulation modelling to the hospital drug distribution system and includes one of the biggest MAE studies carried out in the UK to date. It is the first study of MAEs associated with a PODs system and the first to have compared data obtained from administration records with those obtained using observation. It is only the second recent UK study to have compared different drug distribution systems on the same hospital wards and it is the first to have included all drug rounds during each data collection period, including those at weekends. Finally, it provides the first valid, reliable method for assessing the severity of MAEs identified in observation-based studies.

Following the recent introduction of clinical governance (Department of Health, 1998), NHS trusts will be directly responsible for assessing and minimising the risks of adverse

events. It is likely that MAEs will receive increasing attention in UK hospitals; the findings of the present study are therefore particularly relevant at this time.

The following are the key conclusions:

1. Simulation modelling is a potentially useful approach for studying U-MAEs associated with different drug distribution systems, although the model developed needs further refinement to reflect actual practice rather than stated policy.
2. If four experienced health care professionals each assess MAE severity on a scale numbered from zero to ten, their mean scores are both reliable and valid.
3. The introduction of a patients' own drugs system had little effect on the incidence, types or severity of MAEs on the wards studied.
4. The majority of the MAEs associated with the traditional ward pharmacy system and a patients' own drugs system are of minor clinical significance.
5. Data obtained using administration records have high specificity but low sensitivity and low positive predictive value for the identification of U-MAEs; these limitations must be taken into account in any research that uses this method.
6. Observation has little, if any, effect on the incidence of O-MAEs. Routine interventions made by the observer to prevent errors from occurring also have little impact. However a more dramatic intervention, which increased awareness of MAEs on the ward concerned, may have reduced the O-MAE rate identified.

Appendix 1

**Assumptions made during the construction of
preliminary models for software evaluation purposes**

Appendix One: Assumptions made during the construction of preliminary models for software evaluation purposes

1. Only one medication order can be written at any one time and the times of medication order writing are independent from one another. If these assumptions hold then the times between successive medication orders can be described by the exponential distribution (Law and Kelton, 1991). It was assumed that these patterns were similar Mondays through Fridays.
2. Twenty percent of medication orders are for non-stock drugs which must be dispensed from the pharmacy department.
3. The ward pharmacist visits the ward once each day, and orders any non-stock items that are awaiting supply. In practice, nursing staff sometimes take drug charts to the pharmacy department for dispensing if medication is required urgently. However this does not represent an ideal situation and was therefore excluded from this model. It was instead assumed that all orders for non-stock medication remain unsupplied until the next ward pharmacist's visit. Any medication dispensed by an on-call pharmacist when the pharmacy department was closed was also excluded.
4. It was assumed that the time taken for the pharmacist to examine all medicine charts and return to the pharmacy department varies according to an Erlang distribution with a mean of 43 minutes and a shape parameter of 6 (Batty and Dhillon, 1997). The duration of the second visit in the case of the twice daily visits can be described by an Erlang distribution with a mean of 18 minutes and a shape parameter of 2 (Batty and Dhillon, 1997).
5. In the pharmacy department, medication orders await dispensing. Medication is

dispensed by a technician and checked by a pharmacist. Dispensing occurs on a 'first-in-first-out' basis. The time between orders arriving in the dispensary and the completion of the dispensing and checking procedures varies according to an Erlang distribution with a shape parameter of 2 and a scale parameter of 35 minutes (in-house data from the study hospital).

6. The pharmacy department is open between 8.30 am and 5.30 pm daily, Mondays to Fridays. It was assumed that medication orders could not be dispensed outside these times, except that pharmacy staff would not leave in the evening until all medication orders in the department had been dispensed. Weekends were not included in the model, as pharmacy opening hours and ward pharmacy services differ at weekends.

7. Dispensed medication is returned to the ward by porters who leave the pharmacy department at noon and at 5.30 pm. Delivery to the wards takes thirty minutes.

8. It is assumed that each pharmacist visits only one ward.

Appendix 2

Preliminary model constructed using Extend

Appendix Two: Preliminary model constructed using Extend for software evaluation purposes

The on-screen appearance of the model is shown in figures A2.1, A2.2 and A2.3; the following report gives the settings used in each block. A key to the Extend blocks used is included in Appendix 6.

1. Main part of model

Block Label: Executive

Executive block number 0

Input Parameters:

Simulation stops at end time (timed)
Items to Initially Allocate = 100
Group Size for Additional Item Allocations = 100
Number of Attributes for Each Item = 1

Block Label: Generate orders

Generator block number 52

Input Parameters:

Function = Exponential
Parameter 1 = 10.5
Parameter 1 input used
Parameter 2 = 1
Item quantity = 1

Block Label: Mean interval

Input Data block number 3

Input Parameters:

Time units = time units
Stepped
Sets output to zero when out of range
Repeats every 24 time units

Table:	time	y out
	0	10.5
	1	10.5
	2	10.5
	3	10.5
	4	10.5
	5	10.5

6	10.5
7	10.5
8	0.267
9	0.267
10	0.267
11	0.267
12	0.3
13	0.3
14	0.3
15	0.3
16	0.617
17	0.617
18	1.08
19	1.08
20	1.08
21	1.08
22	1.08
23	1.08
24	1.08

Block Label: **Buffer**

Resource block number 4

Input Parameters:

Initial Available = 0

Block Label: **Is it stock?**

Input Random Number block number 5

Random selection of stock (value 0) or non-stock (value 1) items

Input Parameters:

Distribution = General

Values are Discrete

Table: Value Probability

0 0.8

1 0.2

Block Label: **Routing**

Select DE Output block number 2

Input Parameters:

Select connector chooses the output

The top output is chosen by a zero

Invalid selects reject inputs

Do not change animation pictures

Block Label: **Exit stock item**

Exit block number 6

Block Label: Non-stock items time stamped

Timer block number 9

Input Parameters:

Do not change animation pictures

Block Label: Await pharmacist

Resource block number 7

Input Parameters:

Initial Available = 0

Block Label: Time of porter

Input Data block number 26

Outputs value of one when the porter is available, else outputs a zero

Input Parameters:

Time units = time units

Stepped

Sets output to zero when out of range

Repeats every 24 time units

Table:	time	y out
	0	0
	12	1
	12.08	0
	17.5	1
	17.58	0
	20	1
	20.08	0

Block Label: Porters

Activity, Service block number 27

Input Parameters:

Do not change animation pictures

Block Label: Porter duration

Activity, Multiple block number 31

Input Parameters:

Delay = generic time units

Last Delay Used = 0.5 generic time units

Maximum Number in Activity = 1000

Do not change animation pictures

Block Label: End

Exit block number 32

TIMER OUTPUTBlock Label: **Mean delay**

Mean & Variance block number 1

Input Parameters:

Uses n-1 (sample)

Clear statistics at time: 48

Block Label: **Mean all runs**

Mean & Variance block number 62

Input Parameters:

Uses n-1 (sample)

Calculate for multiple simulations

Clear statistics at time: 0

2. Ward pharmacist submodelBlock Label: **Time of day**

Input Data block number 105

Outputs a value of one for the afternoon visit, else a zero

Input Parameters:

Time units = time units

Stepped

Sets output to zero when out of range

Repeats every 24 time units

Table: time y out

0 0

12 0

13.75 1

14.75 0

17.58 0

Block Label: **Routing**

Select DE Output block number 71

Input Parameters:

Select connector chooses the output

The top output is chosen by a 0

Invalid selects default to bottom output

Do not change animation pictures

Block Label: **Full visit**

Activity, Multiple block number 15

Input Parameters:

Delay = generic time units

Last Delay Used = 0.38654447588438 generic time units

Maximum Number in Activity = 1000

Do not change animation pictures

Block Label: Walk on visit

Activity, Multiple block number 70

Input Parameters:

Delay = generic time units

Last Delay Used = 0.17808141699492 generic time units

Maximum Number in Activity = 1000

Do not change animation pictures

Block Label: Time for visit (1)

Input Random Number block number 16

Input Parameters:

Distribution = Erlang

Parameter 1 = 0.72

Parameter 2 = 6

Parameter 3 = 1

Block Label: Time for visit (2)

Input Parameters:

Distribution = Erlang

Parameter 1 = 0.3

Parameter 2 = 2

Parameter 3 = 1

Block label: Combine

Combine block number 72

Input Parameters:

Do not change animation pictures

3. Dispensing submodel**Block Label: Queue**

Queue, FIFO block number 8

Input Parameters:

Maximum Queue Length = 1000

L and W are: continuous

Do not change animation pictures

Block Label: Is dispensary open?

Activity, Service block number 35

Input Parameters:

Do not change animation pictures

Block Label: Opening times

Input Data block number 36

Input Parameters:

Time units = time units

Stepped

Sets output to zero when out of range

Repeats every 24 time units

Table:	time	y out
	0	0
	8.5	1
	17.5	0

Block Label: Buffer

Resource block number 39

Input Parameters:

Initial Available = 0

Block Label: Dispensing

Activity, Multiple block number 17

Input Parameters:

Delay = generic time units

Last Delay Used = 0.90387267459527 generic time units

Maximum Number in Activity = 1000

Do not change animation pictures

Block Label: Time to wait

Input Random Number block number 18

Input Parameters:

Distribution = Erlang

Parameter 1 = 1.167

Parameter 2 = 2

Parameter 3 = 1

Block Label: Porters box

Resource block number 25

Input Parameters:

Initial Available = 0

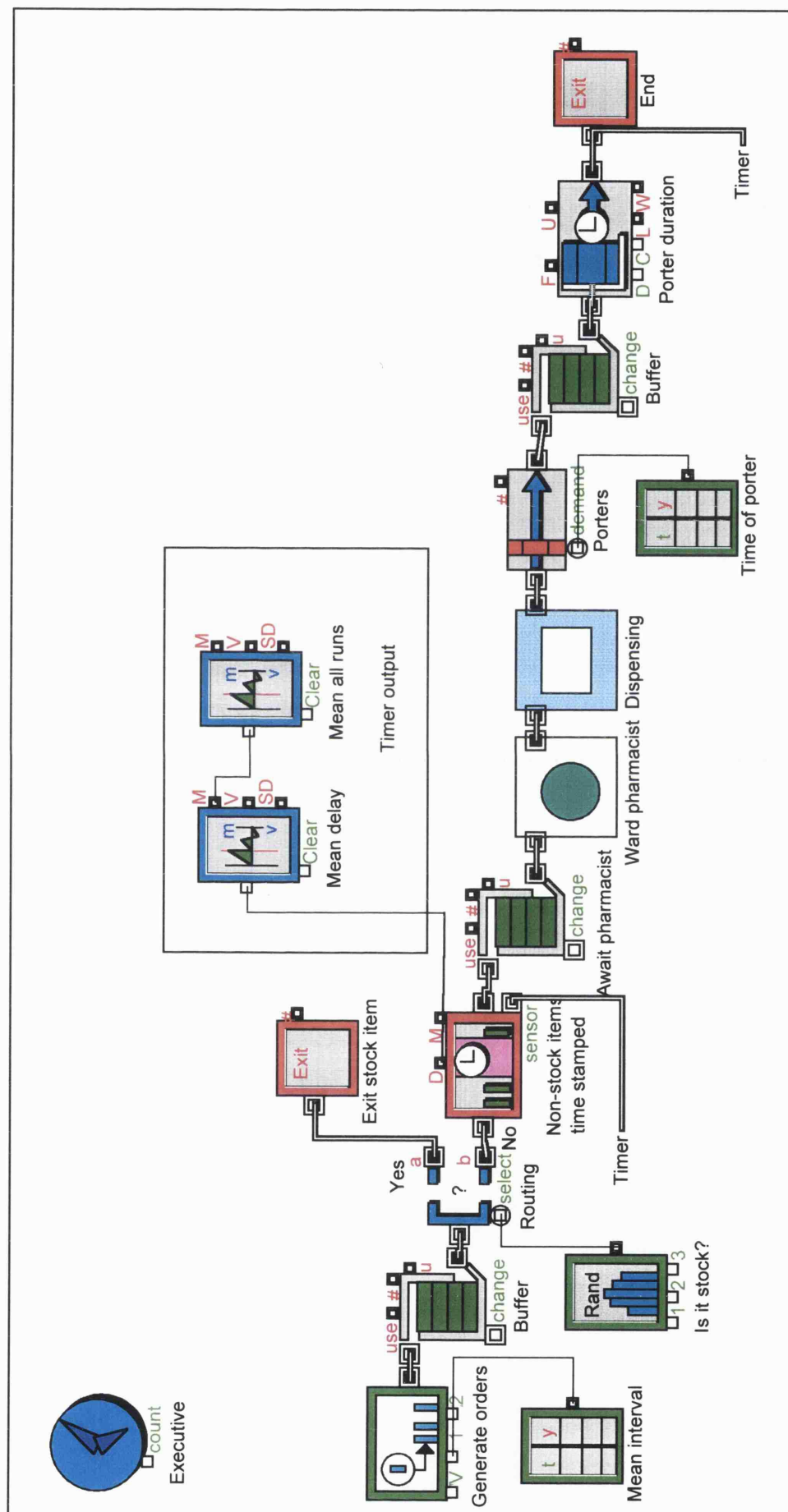


Figure A2.1 On-screen appearance of preliminary Extend model.

The 'Ward pharmacist' and 'Dispensing' blocks represent submodels; these are shown in figures A2.2 and A2.3.

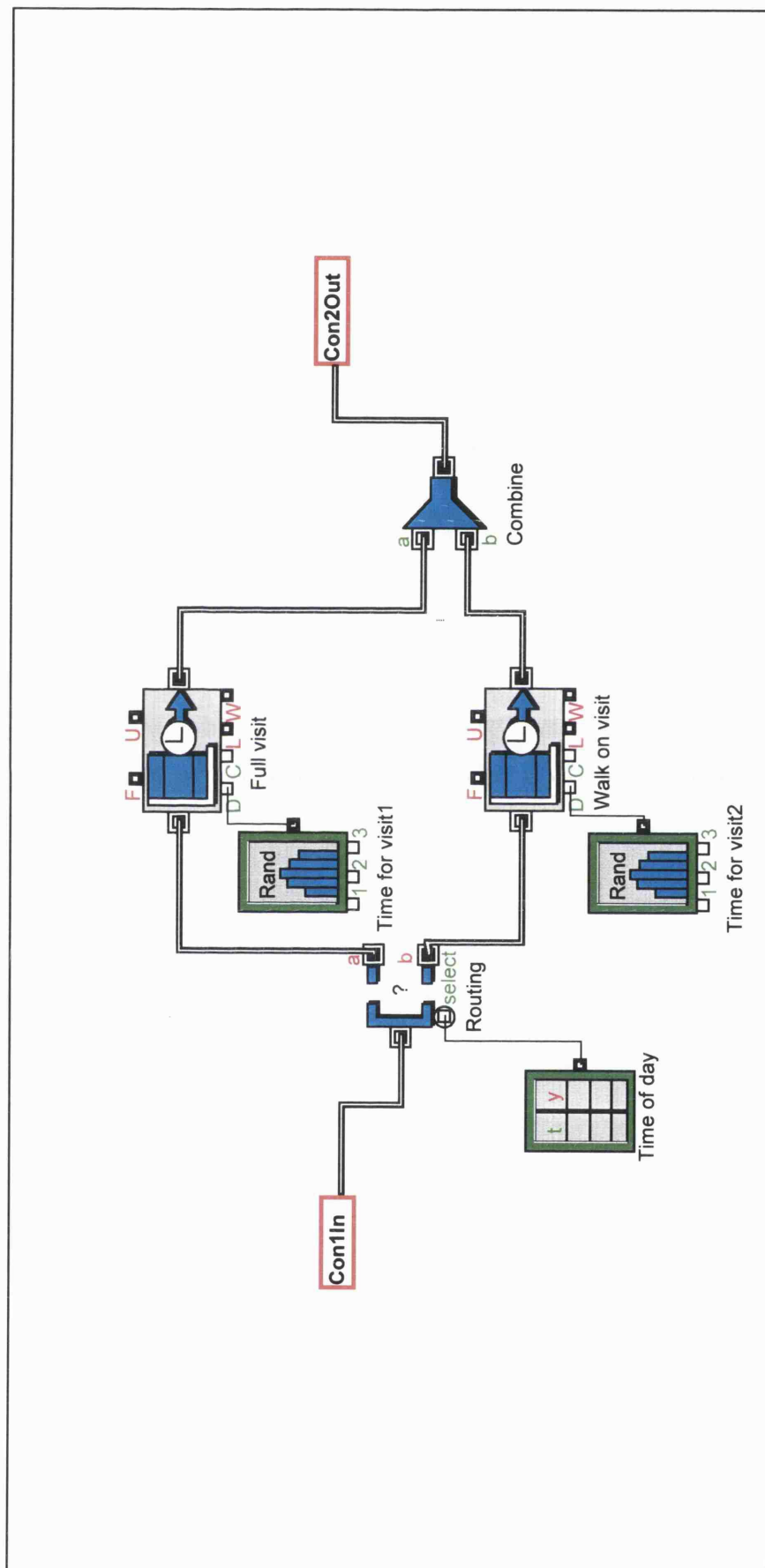


Figure A2.2 Ward pharmacist submodel.

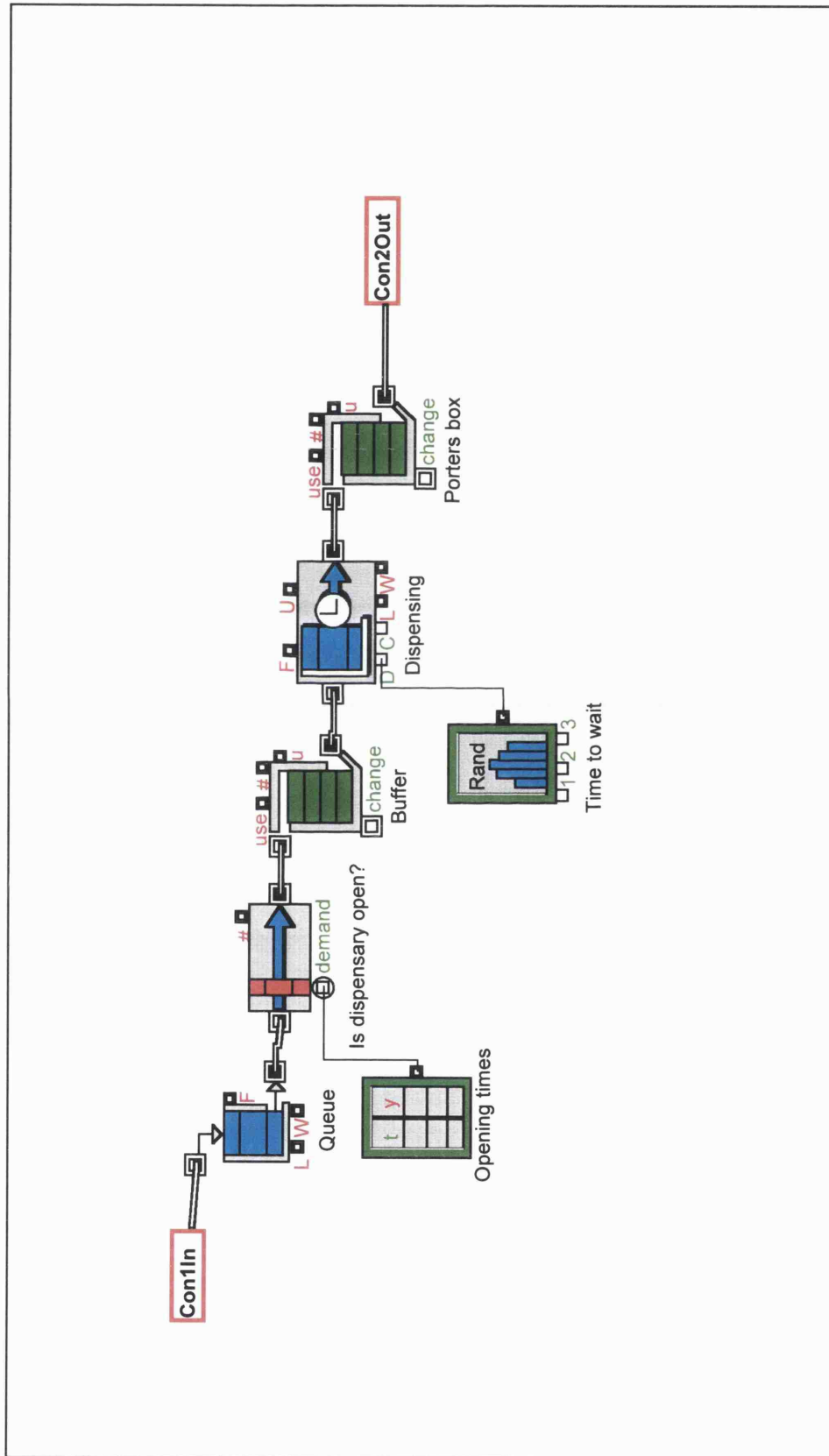


Figure A2.3 Dispensing submodel.

Appendix 3

Preliminary model constructed using Ithink

Appendix Three: Preliminary model constructed using Ithink for software evaluation purposes

The on-screen appearance of the model is shown in figure A3.1; the following report gives the equations used in each part of the model.

1. Prescription-writing sector

Clock = COUNTER(0,1440)

Mean_rate = IF(Clock>=0) AND(Clock<420) THEN 0.0027 ELSE IF (Clock>=420) AND (Clock < 540) THEN 0.087 ELSE IF (Clock >= 540) AND (Clock < 660) THEN 0.0013 ELSE IF (Clock >= 660) AND (Clock < 780) THEN 0.018 ELSE IF (Clock >= 780) AND (Clock < 900) THEN 0.0095 ELSE IF (Clock >= 900) AND (Clock <1020) THEN 0.0067 ELSE IF (Clock >= 1020) AND (Clock <1140) THEN 0.018 ELSE 0.0027

NS_items_written = POISSON(Mean_rate)

Non_stock_items(t) = Non_stock_items(t - dt) + (NS_items_written - Transcription) * dt
INIT Non_stock_items = 4

2. Ward sector

Transcription = IF(Clock=540) OR (Clock = 840) THEN (Non_stock_items)
ELSE 0

Pharmacist(t) = Pharmacist(t - dt) + (Transcription - Travel_to_dispensary) * dt
INIT Pharmacist = 0

TRANSIT TIME = varies

INFLOW LIMIT = INF

CAPACITY = INF

Travel_to_dispensary = CONVEYOR OUTFLOW

TRANSIT TIME = IF(Clock > 825) AND (Clock < 885) THEN (EXPRND (9.04) + EXPRND (9.04)) ELSE (EXPRND (7.21) + EXPRND (7.21) + EXPRND (7.21) + EXPRND (7.21) + EXPRND (7.21) + EXPRND (7.21))

3. Dispensary sector

Dispensary(t) = Dispensary(t - dt) + (Travel_to_dispensary - Dispensing) * dt
INIT Dispensary = 0

TRANSIT TIME = varies

INFLOW LIMIT = INF

CAPACITY = INF

Dispensing = CONVEYOR OUTFLOW

TRANSIT TIME = EXPRND(35)+EXPRND(35)

Porter's_box(t) = Porter's_box(t - dt) + (Dispensing - Delivery_to_ward) * dt

INIT Porter's_box = 0

4. Delivery to ward sector

Delivery_to_ward = DELAY(Porter's_time, 30)

Delay_time = CTMEAN(Delivery_to_ward,1000,1)

Porter's_time = IF(Clock = 720) OR (Clock = 1050) OR (Clock = 1200)
THEN Porter's_box ELSE 0

Standard_Deviation = CTSTDDEV(Delivery_to_ward,1)

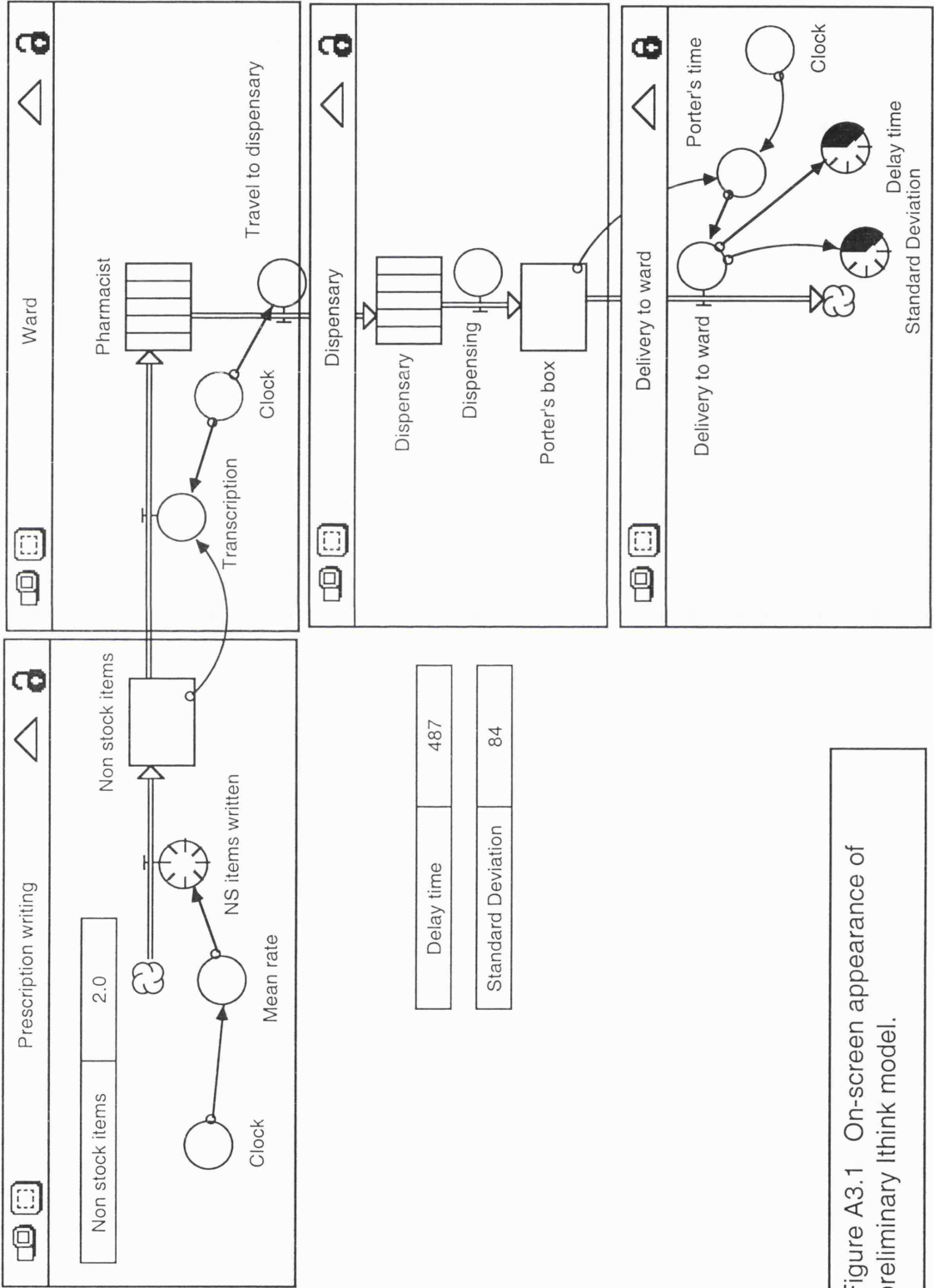


Figure A3.1 On-screen appearance of preliminary Ithink model.

Appendix 4

Preliminary model constructed using Simul8

Appendix Four: Preliminary model constructed using Simul8 for software evaluation purposes

The on-screen appearance of the model is shown in figure A4.1; the following settings were used in each block.

Prescription (Rx) writing

Generates simulation items according to the distribution 'Prescription writing'. This is defined as the following time-dependent distribution:

Time	Distribution
00:00 - 08:00	Exponential with mean of 630 minutes
08:00 - 12:00	Exponential with mean of 16 minutes
12:00 - 16:00	Exponential with mean of 18 minutes
16:00 - 18:00	Exponential with mean of 37 minutes
18:00 - 00:00	Exponential with mean of 65 minutes

The simulation items generated are also time-stamped.

Routing

This block randomly selects 20% of the simulation items and routes these to the 'Await pharmacist' block. The remaining 80% are passed to the 'Stock items' block.

Stock items

This block removes simulation items from the model.

Pharmacist

The 'pharmacist' resource is set up so as to be available only at certain times, using the 'shift patterns' facility. The shift patterns were set to correspond to the times of the ward pharmacists' visits.

Transcription

This block was set up so that simulation items were allowed to pass through only when a pharmacist was available.

Transfer to pharmacy

This block delays the simulation items for a time randomly drawn from the appropriate distribution of visit times.

Dispensing

Simulation items are delayed for a time randomly drawn from the appropriate dispensing time distribution.

Porter's boxes

This is a storage block, which holds the simulation items until they are processed by the 'Pick up porters' boxes' block.

Porter

The porter resource is set up so as to be available only at the times of the porters' visits, using the 'shift patterns' facility.

Pick up porter's boxes

This block allows simulation items to pass through only when a porter is available.

Transfer to wards

Simulation items are delayed for an appropriate time while they are delivered to the ward.

Non-stock items supplied

Simulation items exit the model and the time spent within the system calculated.

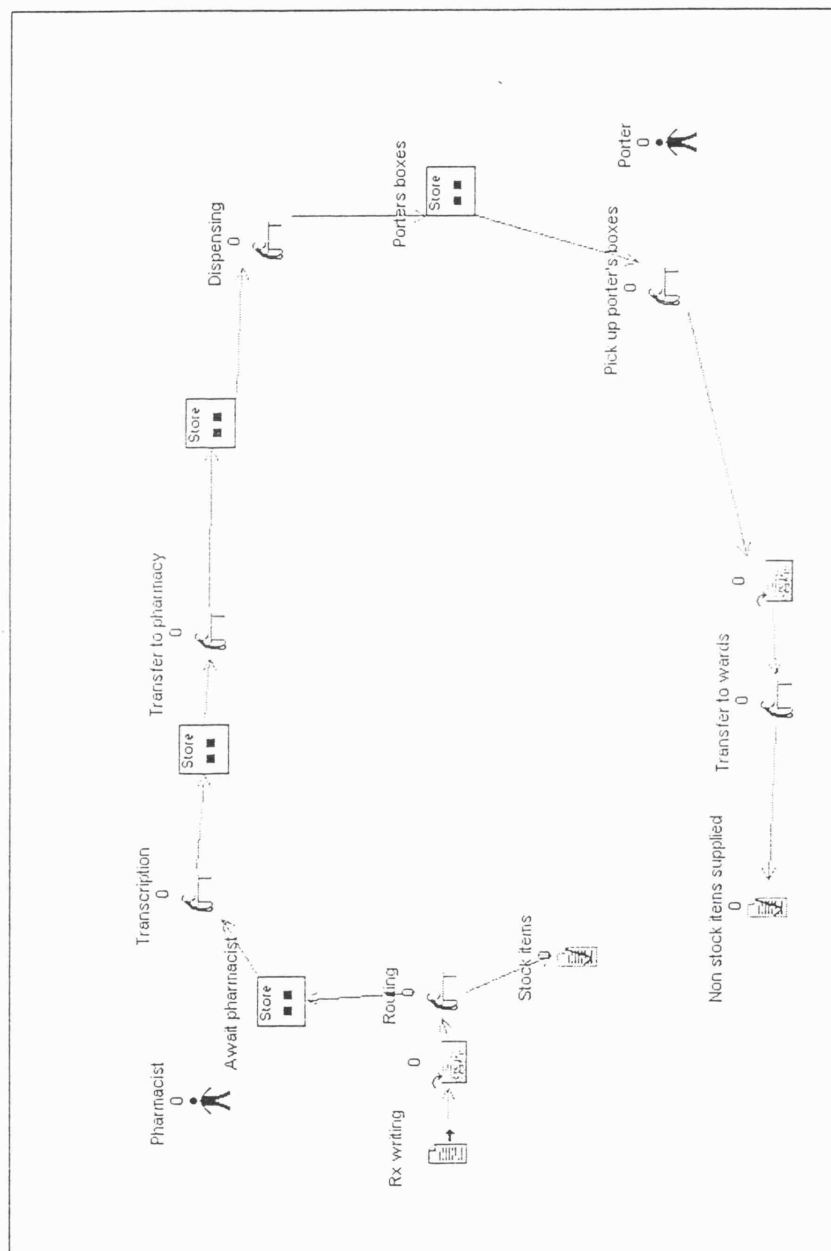


Figure A4.1 On-screen appearance of preliminary Simul8 model.

Appendix 5

Data collection form used to record prescription events

Details of prescribing events per patient

Ward:	Date & time of admission:	Bed Number:
Initials:	Date & time of discharge:	
Hosp number:	Elective/Non-elective:	
Consultant:	Number of regularly Rxed items at discharge:	

[illegible]

Previous prescribing events

Drug	Date started	Day of admission	Date stopped	Day of admission	Comments

Appendix 6

Detailed description of the final simulation model

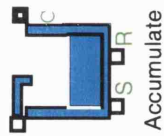
Appendix Six: Detailed description of the final simulation model

The final version of the model was constructed using Extend+Manufacturing version 4.0.3a (ImagineThat! Inc, San Jose, California, USA). About 300 Extend blocks were used in its construction. A fold-out diagram of the whole base case model is included inside the back cover of this thesis; this appendix describes the function of each block and shows its on-screen appearance on a sector-by-sector basis.

Throughout this appendix, the types of Extend blocks are given in italics and the names given to individual blocks in inverted commas. A pictorial key to the blocks used is given in Figure A6.1. In all model diagrams, single lines represent the flow of information; double lines represent the flow of simulation items. Inputs to each block are shown as unshaded connectors, outputs as black connectors. The simulation runs from left to right.

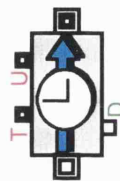
Many *resource* blocks are present throughout the model; these serve as buffers between successive processes and will not be mentioned individually. In all of these *resource* blocks, the 'strip attributes from incoming items' option is not selected, so that simulation items retain their attributes throughout the model. Throughout the simulation, time units are hours. The random number generator selected was the minimum standard random number generator, as recommended in the Extend manual (anonymous, 1997). A *random seed control* block controlled the generation of random numbers so that common random numbers could be used when comparing alternative configurations.

The remainder of this appendix gives a detailed description of the base case model on a sector-by-sector basis. Within each sector, the function of each block will be described in turn, beginning at the left hand side of the sector.



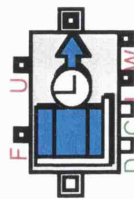
Sums the values input and outputs the total

Accumulate



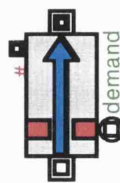
Holds an item for a specified time period, then releases it

Activity, delay



Holds multiple items, based on the delay time for each item

Activity, multiple



Passes items through only when the 'demand' connector is activated

Activity, service

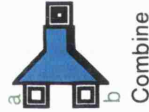


Adds the three inputs and outputs the total

Add

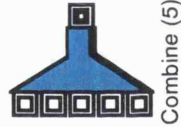


'Catches' items sent by 'throw' blocks



Combines items from two sources into a single stream

Combine

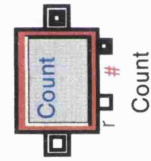


Combines items from five sources into a single stream



Outputs a constant value

Constant



Counts the number of items that pass through

Figure A6.1 Key to Extend blocks used.

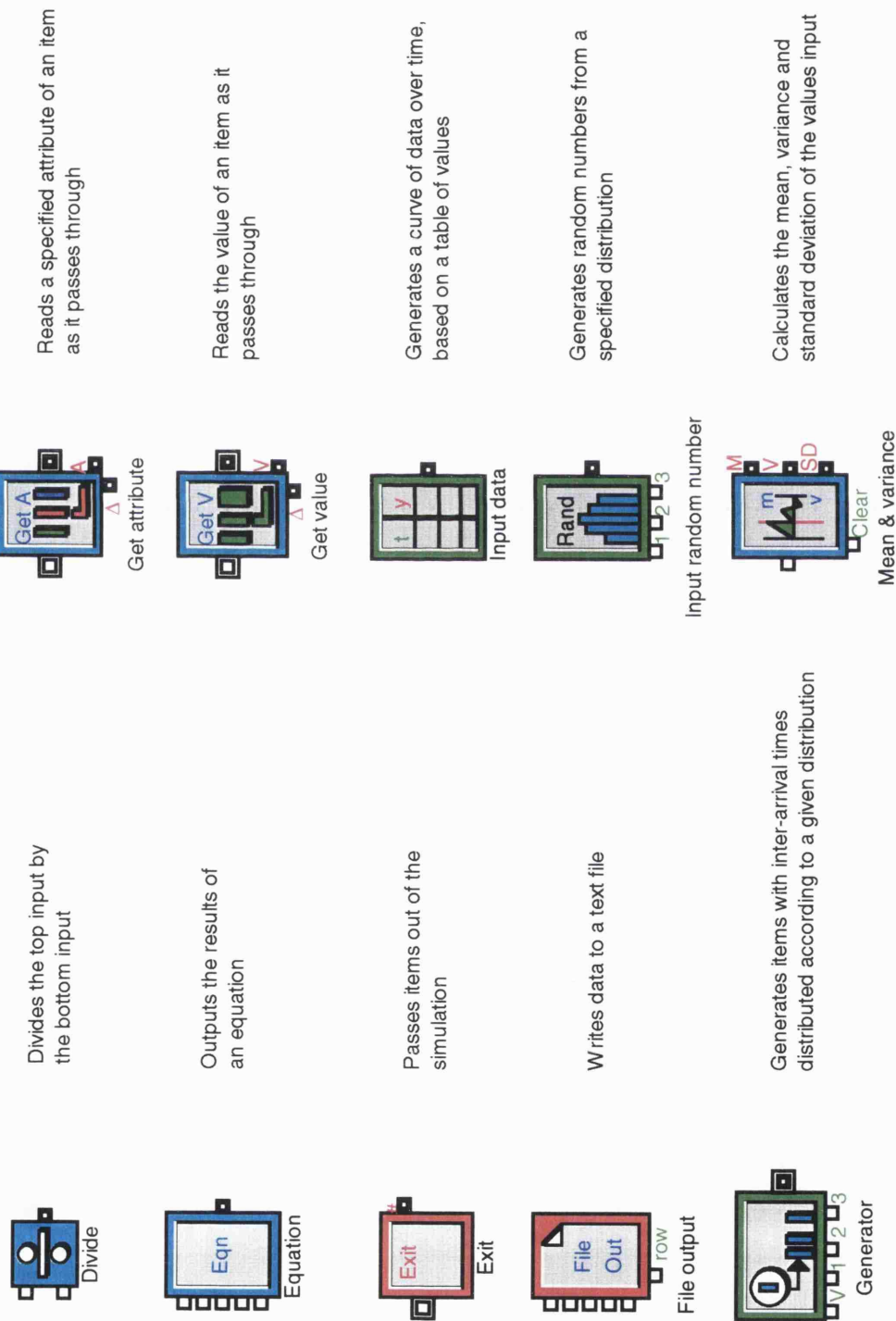


Figure A6.1 Key to Extend blocks used (continued).

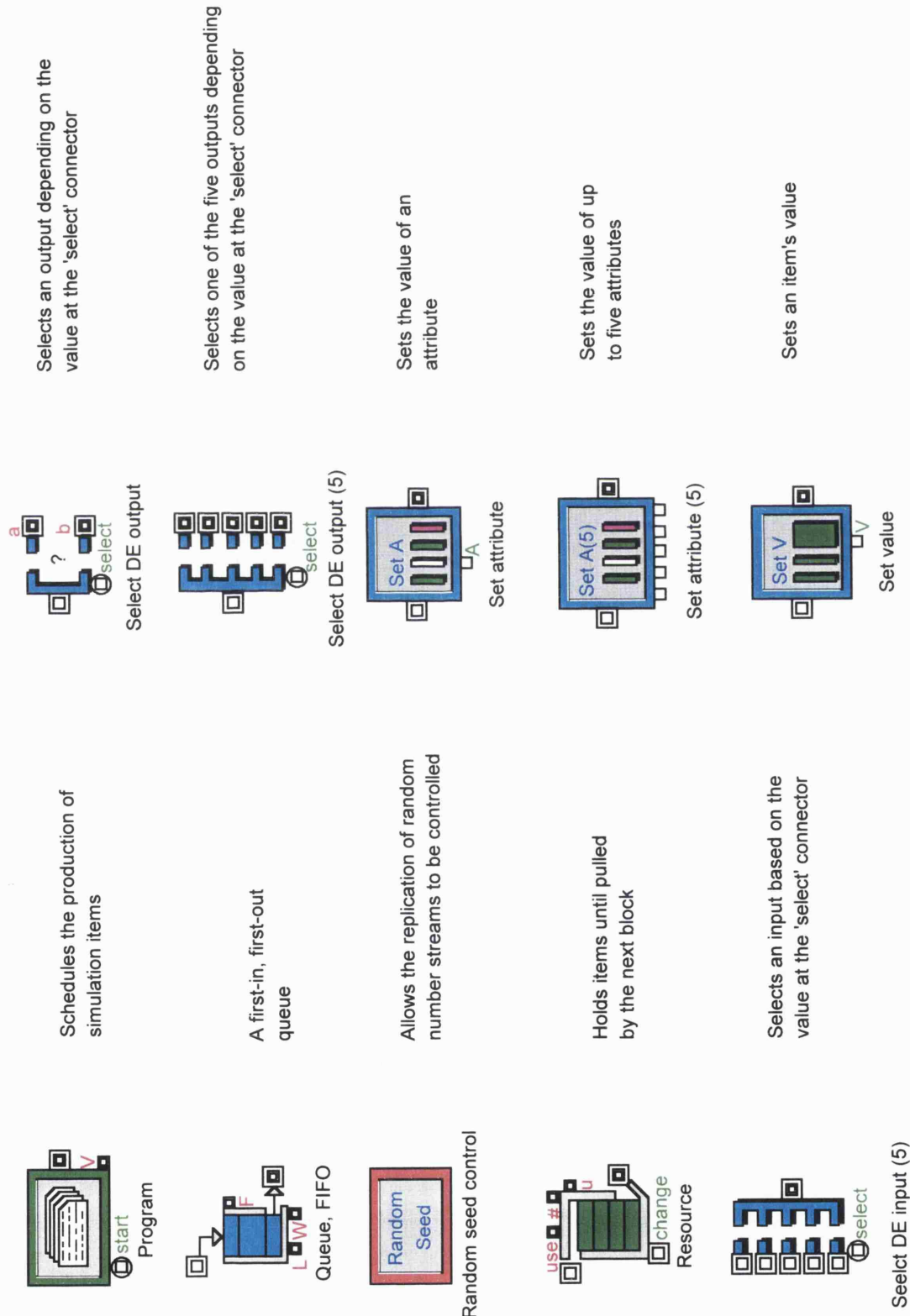


Figure A6.1 Key to Extend blocks used (continued).

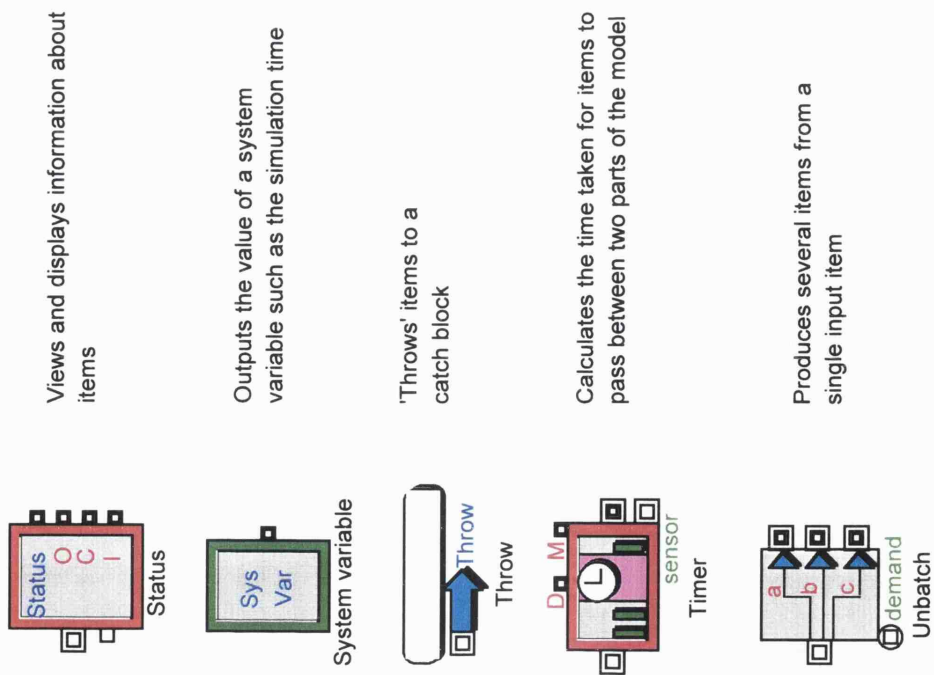


Figure A6.1 Key to Extend blocks used (continued).

Sector 0: Control of the simulation

The *executive* block (figure A6.2) controls the simulation. This was set up to control the duration of the simulation according to the end time specified, rather than by the number of elapsed events. According to recommended procedures {1157}, 5800 items were initially allocated to the simulation; additional items were allocated in groups of 100. For efficiency, attribute information was stored in arrays rather than as strings.

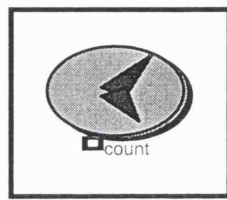


Figure A6.2
Executive block.

Sector 1: Patient admissions and discharges

This sector represents ward admissions and discharges; its on-screen appearance is shown in figure A6.3. In this sector, each simulation item represents one patient. The *generator* block 'admissions' generates simulated patients with inter-arrival times distributed according to an exponential distribution. This block is set up so that no item is produced at time zero and changes to inter-arrival time occur immediately. The mean of the exponential distribution is input by the *input data* block 'inter-arrival times'; this changes according to time of day and day of week (table A6.1). These figures were derived from empirical data as described in section 4.7 and discussed in section 5.2.2. The output of the *input data* block is stepped, rather than interpolated.

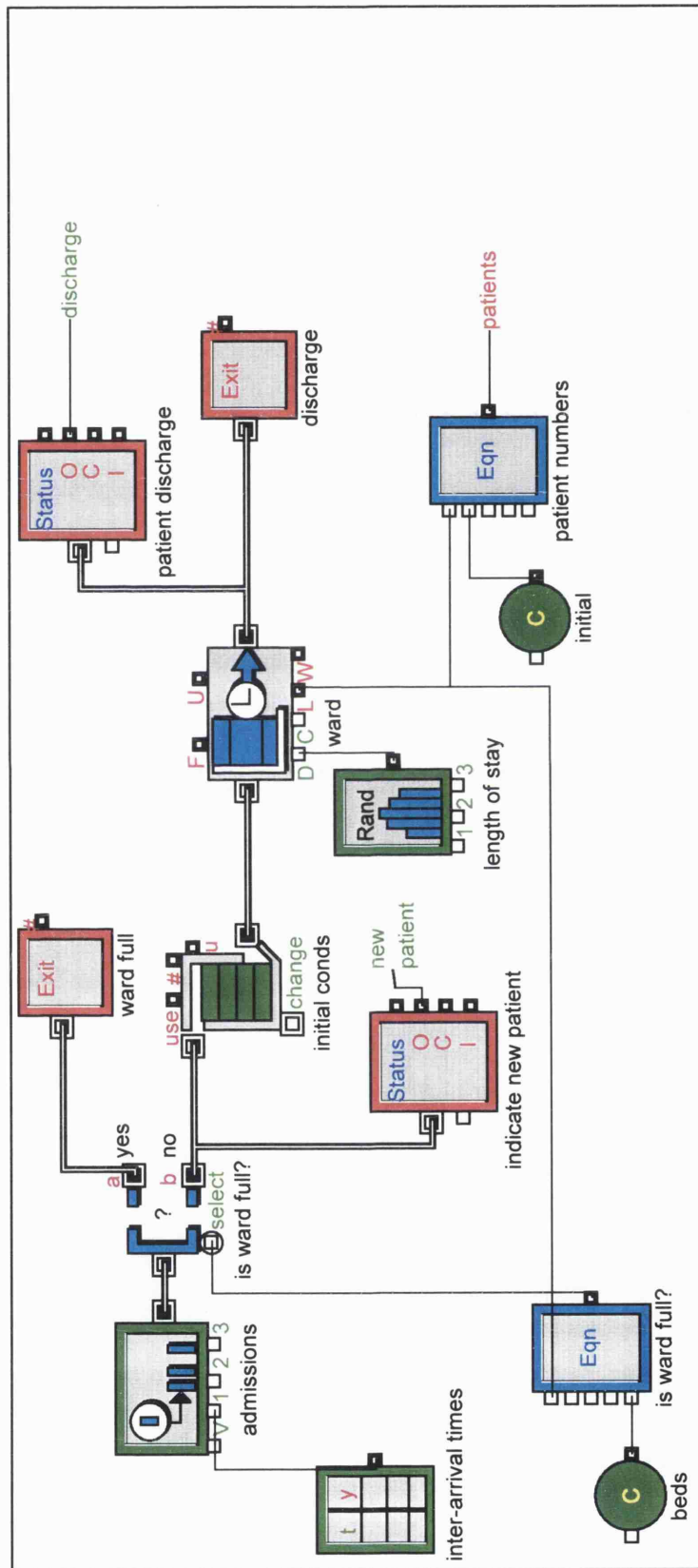


Figure A6.3 Sector 1: Patient admissions and discharges.

The *select discrete event output* block ‘is ward full?’ ensures that the number of simulated patients on the ward does not exceed the number of beds. The top output from this block is chosen if the value at the ‘select’ connector is zero; the bottom output is chosen otherwise. The top output leads to the *exit* block ‘ward full’ and represents patients who cannot be admitted because the ward is full. The *equation* block ‘is ward full?’ is used to determine the value at the ‘select’ connector. This block reads the number of patients on the simulated ward, and outputs either a zero or a one according to the following equation: $\text{IF (PATIENTS < BEDS) RESULT} = 1; \text{ELSE RESULT} = 0;$. The number of beds on the ward is input at the *constant* block ‘beds’ (28 on the surgical ward; 16 on the medical ward).

The *status* block ‘indicate new patient’ records the output from the *select discrete event output* block ‘is ward full?’ and outputs ‘1’ at its ‘O’ connector each time a simulated patient is admitted. This information is passed to sector 2: ‘Medication order writing for newly admitted patients’ to indicate that a new admission has occurred.

The *resource* block ‘initial conds’ contains a number of simulated patients, equivalent to the mean number on the ward (26 for the surgical ward, 15 for the medical ward), who progress immediately to the ward at the beginning of the simulation. The medication orders associated with these patients are considered in sector 7.

The ward itself is represented by the *activity, multiple* block ‘ward’. The maximum number of items that this block can hold is set to be equal to the number of beds on the study ward (28 on the surgical ward; 16 on the medical ward). The time spent on the ward by each simulated patient is determined by the *input random number* block ‘length of stay’, which outputs values randomly drawn from the distribution of ward lengths of stay (exponential distributions with means of 221 and 161 hours for the surgical and medical wards respectively, as discussed in section 4.8).

The *equation* block ‘patient numbers’ outputs the number of patients on the ward. This information is passed to sectors 3: ‘Medication order writing for existing patients’ and 7: ‘Calculate number of doses due’. This equation block contains the equation: IF

(PATIENTS_ON_WARD == 0) RESULT = INITIAL_NUMBER_OF_PATIENTS;
ELSE RESULT = PATIENTS_ON_WARD;. This ensures that the value output at the beginning of the simulation is the initial number of patients on the ward. Without this step, the number of patients on the ward at the beginning of the simulation is recorded as zero, resulting in an attempted division by zero in sector 3. The *constant* block 'initial' inputs the initial number of patients on the ward (26 on the surgical ward; 15 on the medical ward).

Once a simulated patient has exceeded end of its ward length of stay, it exits the model through the *exit* block 'discharge'. The *status* block 'patient discharge' views the output from the 'ward' block, and outputs a '1' at its 'O' connector each time a patient is discharged. This information is passed to sector 7: 'Calculate number of doses due' to indicate that a patient has been discharged.

Hour of week *	Mean time between admissions (hours)	
	Surgical ward	Medical ward
0	100.0 †	37.0
8	17.9	18.6
10	100.0	100.0
12	100.0	18.6
14	2.2	6.2
16	1.5	2.6
18	2.0	3.1
20	7.2	7.4
24	100.0	37.0
32	17.9	18.6
34	100.0	100.0
36	100.0	18.6
38	2.2	6.2
40	1.5	2.6
42	2.0	3.1
44	7.2	7.4
48	100.0	37.0
56	17.9	18.6
58	100.0	100.0
60	100.0	18.6
62	2.2	6.2
64	1.5	2.6
66	2.0	3.1
68	7.2	7.4
72	100.0	37.0
80	17.9	18.6
82	100.0	100.0
84	100.0	18.6
86	2.2	6.2
88	1.5	2.6
90	2.0	3.1
92	7.2	7.4
96	100.0	37.0
108	100.0	18.6
110	4.0	100.0
112	2.7	18.6

Table A6.1 continues on next page...

Continued from previous page...

114	3.6	6.2
116	12.8	2.6
120	100.0	100.0
132	100.0	4.4
134	6.6	14.0
136	4.4	6.0
138	5.9	7.0
140	21.3	17.0
144	100.0	100.0
152	17.9	41.4
154	100.0	100.0
156	100.0	100.0
158	2.2	14.0
160	1.5	6.0
162	2.0	7.0
164	7.2	17.0
168	100.0	37.0

Table A6.1 Data used in the *input data* block
'inter-arrival times' for each ward.

* where zero is midnight between Sunday night and Monday morning.

† where the probability of a patient being admitted during a given hour was estimated to be zero (section 4.7), a mean inter-arrival time of 100 hours was assumed.

Sector 2: Medication order writing for newly admitted patients

This sector simulates the writing of a drug chart when a patient is admitted. It is illustrated in figure A6.4.

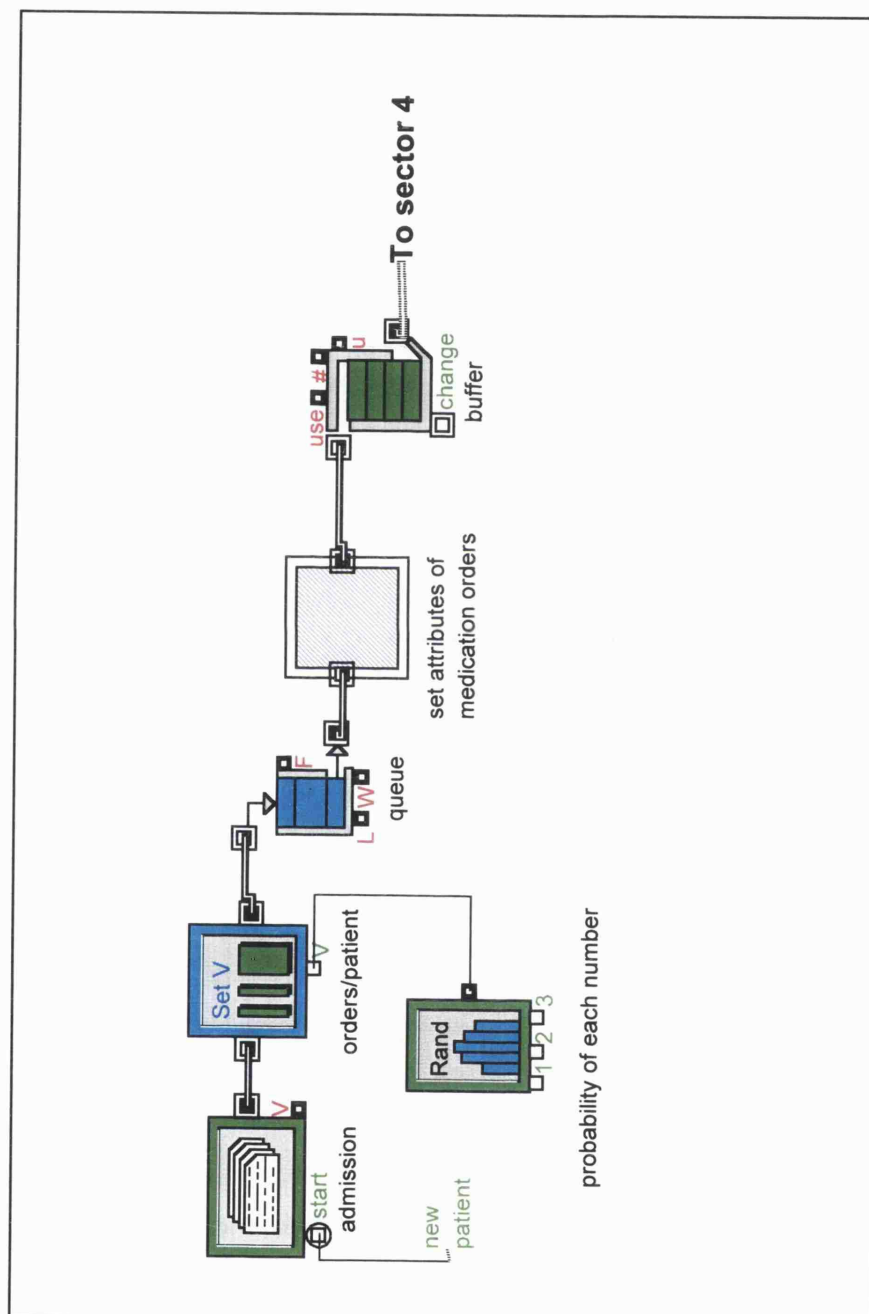


Figure A6.4 Sector 2: Medication order writing for newly admitted patients.

The functions of the 'set attributes of medication orders' submodel are illustrated in figure A6.5.

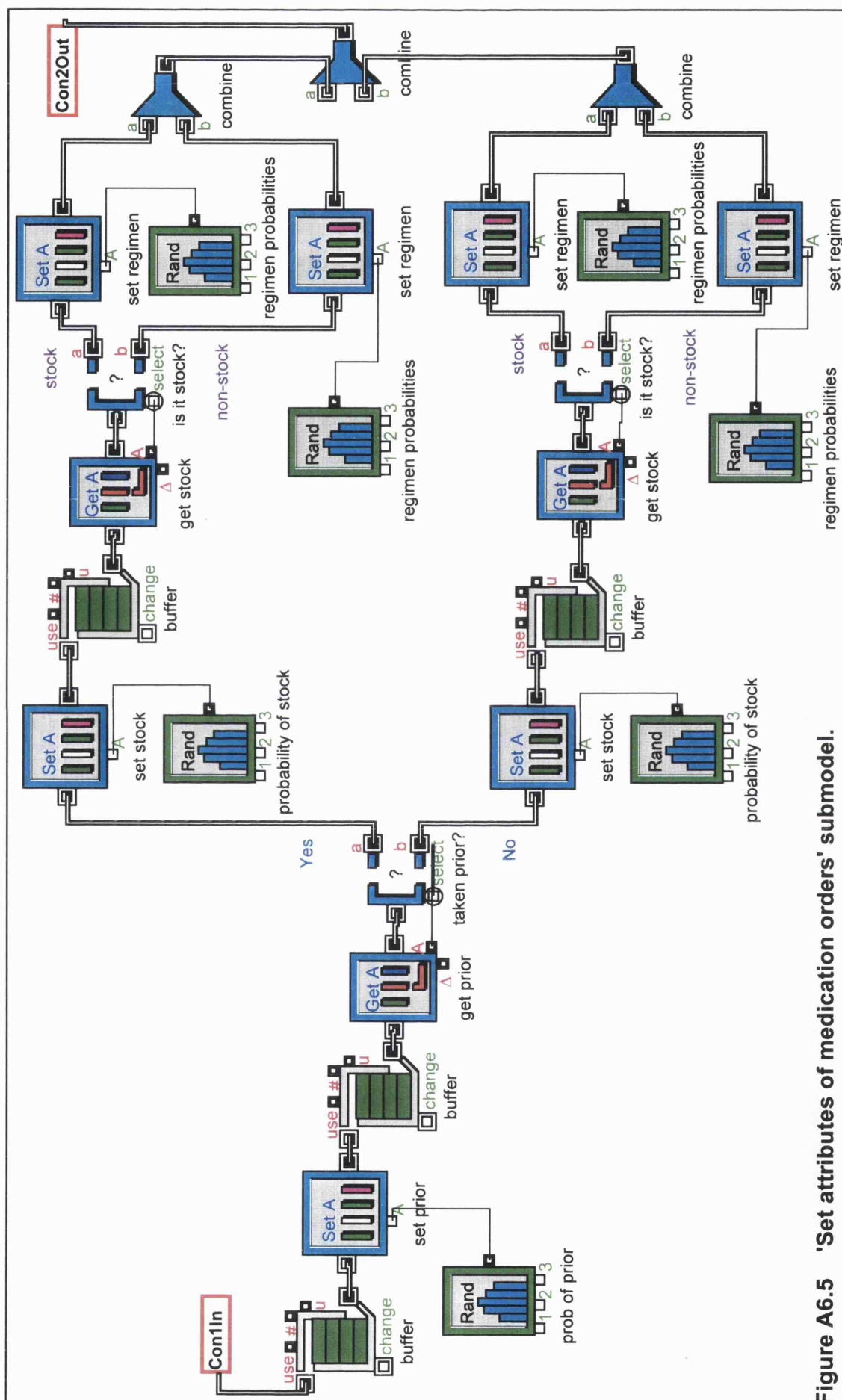
The *program* block ‘admission’ generates one simulation item each time its ‘start’ connector is activated. The ‘start’ connector is activated each time a patient is admitted to the simulated ward in sector 1. The item generated by the *program* block represents the drug chart written for the new patient. The *set value* block ‘orders/patient’ gives each drug chart item a value to represent the number of medication orders on the chart. This number is randomly drawn from the distribution specified in the *input random number* block ‘probability of each number’; this distribution gives the probabilities of different numbers of medication orders being written on admission. In the case of the surgical ward, this was the negative binomial (3, 0.51) distribution. In the case of the medical ward it was the negative binomial (4, 0.45) distribution (section 4.5). The *queue first-in, first-out* block ‘queue’ clones the drug chart items into individual medication orders, depending on the value associated with each drug chart item. In the remainder of the sector, each simulation item therefore represents one medication order.

‘Set attributes of medication orders’ submodel

This submodel (figure A6.5) gives each simulated medication order a series of attributes. These indicate whether or not the order is for a drug that the patient was taking prior to their admission, whether or not the drug is ward stock, and the number of daily doses. The *set attribute* block ‘set prior’ sets the attribute PRIOR, which indicates whether the drug was taken by the patient prior to their admission (PRIOR = 1) or whether the drug was started on admission (PRIOR = 2). Probabilities of each value of PRIOR, as determined in section 4.6, are given in the *input random number* block ‘probability of prior’ (table A6.2).

Value of PRIOR	Surgical ward	Medical ward
1	0.93	0.85
2	0.07	0.15

Table A6.2 Probabilities of each value of the attribute PRIOR, for medication orders written at admission.



Simulated medication orders are then diverted through different sections of the submodel, depending on the value of PRIOR. The *get attribute* block 'get prior' reads the value of PRIOR, which is then output to the 'select' connector of the *select discrete event output* block 'taken prior?' A value of 1 results in the medication order item being diverted via the top output; a value of 2 results in the item passing through the bottom output. The *set attribute* blocks 'set stock' set the attribute STOCK to indicate whether the item prescribed is a stock drug (STOCK = 1) or a non-stock drug (STOCK = 2). The *input random number* blocks 'probability of stock' output the probabilities of each value of STOCK (table A6.3), as determined in section 4.6.

	Surgical ward	Medical ward
Drugs taken prior to admission (PRIOR = 1)		
1	0.52	0.70
2	0.48	0.30
Drugs not taken prior to admission (PRIOR = 2)		
1	1.00	0.75
2	0.00	0.25

Table A6.3 Probabilities of each value of the attribute STOCK, for medication orders written at admission.

Medication order items are again diverted through different paths depending on the value of STOCK, and the attribute REG is set, to indicate the number of times each day the drug is to be administered. REG can be any number from one to four, the probabilities of each of which are set in the *input random number* blocks 'regimen probabilities' (table A6.4), as determined in section 4.6. All medication order items, with their attributes set, are then recombined and can progress to sector 4.

Value of PRIOR	Value of STOCK	Probability of each value of attribute REG			
		1	2	3	4
Surgical ward					
1	1	0.54	0.19	0.08	0.19
0	1	0.43	0.19	0.12	0.26
1	0	0.59	0.20	0.09	0.11
0	0	(There are no orders in this category)			
Medical ward					
1	1	0.56	0.18	0.19	0.08
0	1	0.47	0.17	0.24	0.13
1	0	0.58	0.18	0.19	0.04
0	0	0.49	0.18	0.24	0.09

Table A6.4 Probabilities of each value of the attribute REG, for medication orders written at admission.

Sector 3: Medication order writing for existing patients

This sector simulates the writing of medication orders for previously admitted patients; its on-screen appearance is shown in figure A6.6.

The *generator* block 'Rx writing' generates new medication orders with inter-arrival times randomly drawn from an exponential distribution. No item is produced at time zero and changes to inter-arrival times occur immediately. The mean of the exponential distribution is set according to the *input data* block 'mean interval', which contains values for the mean time between successive medication orders written per patient, according to time of day and day of week. These values were determined from empirical data as described in section 4.5 and are shown in table A6.5. Output is stepped, rather than interpolated. The mean interval is divided by the number of patients present on the ward, to give the mean interval between successive medication orders for the whole ward. Information concerning the current number of patients on the ward is obtained from

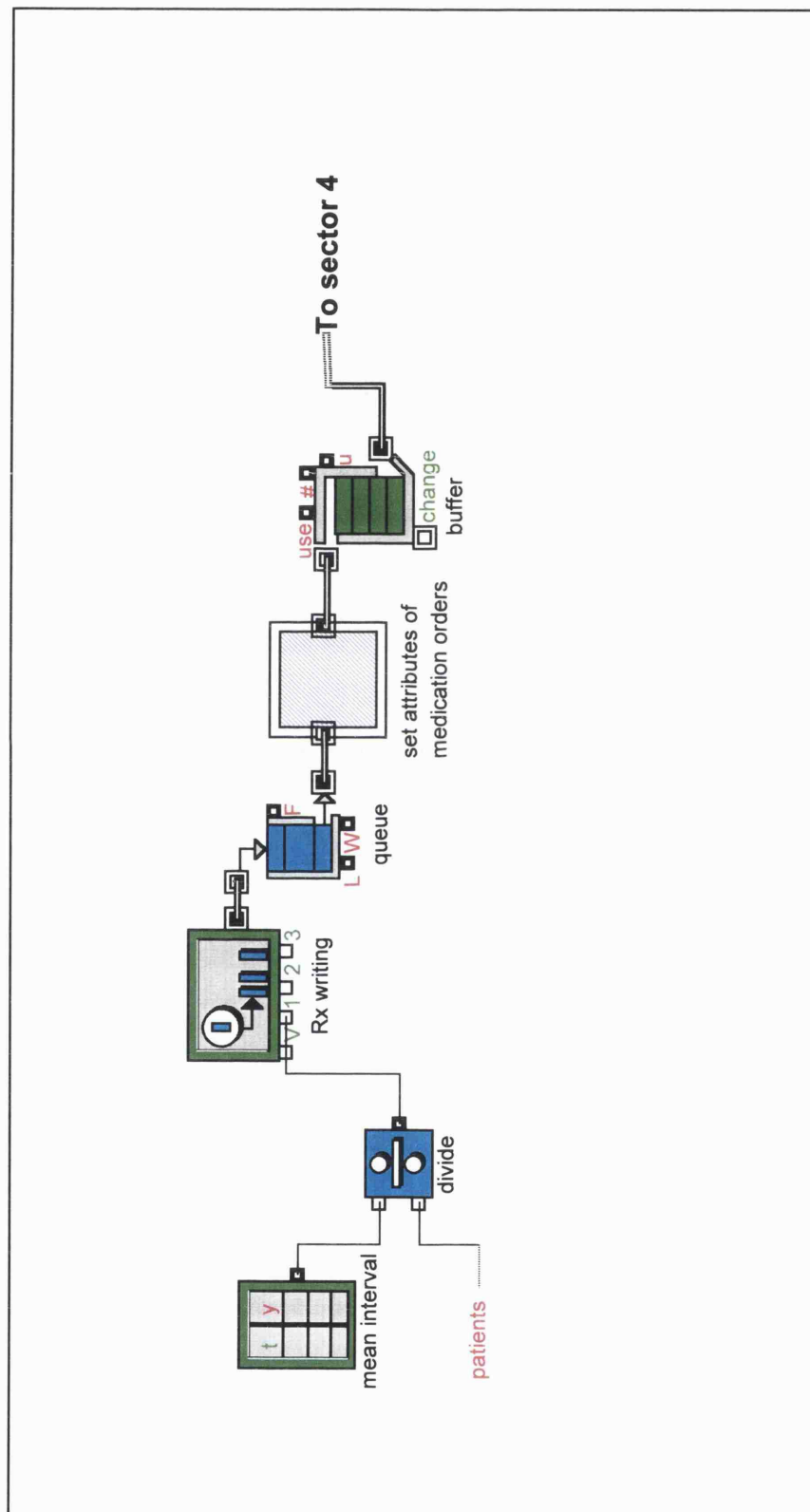


Figure A6.6 Sector 3: Medication order writing for existing patients.

The functions of the 'set attributes of medication orders' submodel are illustrated in figure A6.5.

sector 1. The number of new medication orders generated therefore varies according to the number of patients on the ward, the time of day and the day of the week. Medication order items then pass through the *queue, first in - first out* block 'queue' before entering the 'set attributes of medication orders' submodel.

Time of day (24 hour clock)	Surgical ward		Medical ward	
	Mon - Fri	Sat & Sun	Mon - Fri	Sat & Sun
00	2000 *	2000	1000	1000
06	1667	2000	1000	1000
07	270	2000	150	1000
08	77	368	38	60
09	33	368	23	60
10	24	368	21	60
11	27	368	23	60
12	57	2000	32	60
13	115	2000	35	60
14	77	2000	33	60
15	46	2000	27	60
16	24	2000	18	1000
17	24	2000	18	1000
18	31	2000	200	1000
19	42	2000	600	1000
20	71	2000	100	1000
21	153	2000	86	1000
22	917	2000	120	1000
23	2000	2000	300	1000

Table A6.5 Mean inter-arrival times between successive medication orders written for existing patients on each simulated ward.

* Values are for the inter-arrival times, in hours, between successive medication orders written per patient. These are the reciprocals of the mean number of medication orders written per patient per hour.

'Set attributes' submodel

The attributes STOCK, PRIOR and REG are set for each simulated medication order, in a similar manner to that described for sector 2. Probabilities of each value of the PRIOR, STOCK and REG attributes are shown in tables A6.6 to A6.8. There was no interaction between the values of PRIOR and STOCK for medication orders written subsequent to admission.

Value of PRIOR	Surgical ward	Medical ward
1	0.08	0.04
2	0.92	0.96

Table A6.6 Probabilities of each value of the attribute PRIOR, for medication orders written for existing patients.

Value of STOCK	Surgical ward	Medical ward
1	0.85	0.75
2	0.15	0.25

Table A6.7 Probabilities of each value of the attribute STOCK, for medication orders written for existing patients.

Value of PRIOR	Value of STOCK	Probability of each value of REG attribute			
		1	2	3	4
Surgical ward					
1	1	0.44	0.19	0.21	0.25
0	1	0.33	0.19	0.16	0.32
1	0	0.49	0.20	0.13	0.17
0	0	0.38	0.20	0.17	0.24
Medical ward					
1	1	0.56	0.18	0.19	0.08
0	1	0.47	0.17	0.24	0.13
1	0	0.58	0.18	0.19	0.04
0	0	0.49	0.18	0.24	0.09

Table A6.8 Probabilities of each value of the attribute REG, for medication orders written for existing patients.

Sector 4: Determine whether item is available on ward

This sector determines whether or not simulated medication orders are for ward stock drugs and thus available for administration. It is illustrated in figure A6.7.

Simulated medication orders arrive from sectors 2 and 3. The *unbatch* block ‘make duplicate’ creates a duplicate of each medication order item that passes through. One of the duplicate items is then transferred via the *throw* block ‘doses due’ to sector 7, so that the number of doses due can be calculated. The other item then passes on to the *timer* block ‘time stamp’ which records the time of each simulated medication order that passes through. Once the simulated medication order is supplied in sector 6, that time is also recorded so that the *timer* block can calculate the time that each spends in the system. The *mean & variance* block ‘mean delay’ calculates the mean delay time for all simulated medication orders that have to be dispensed. The *count items* block ‘count new Rx’ counts the simulated medication orders that pass through this part of the model. This

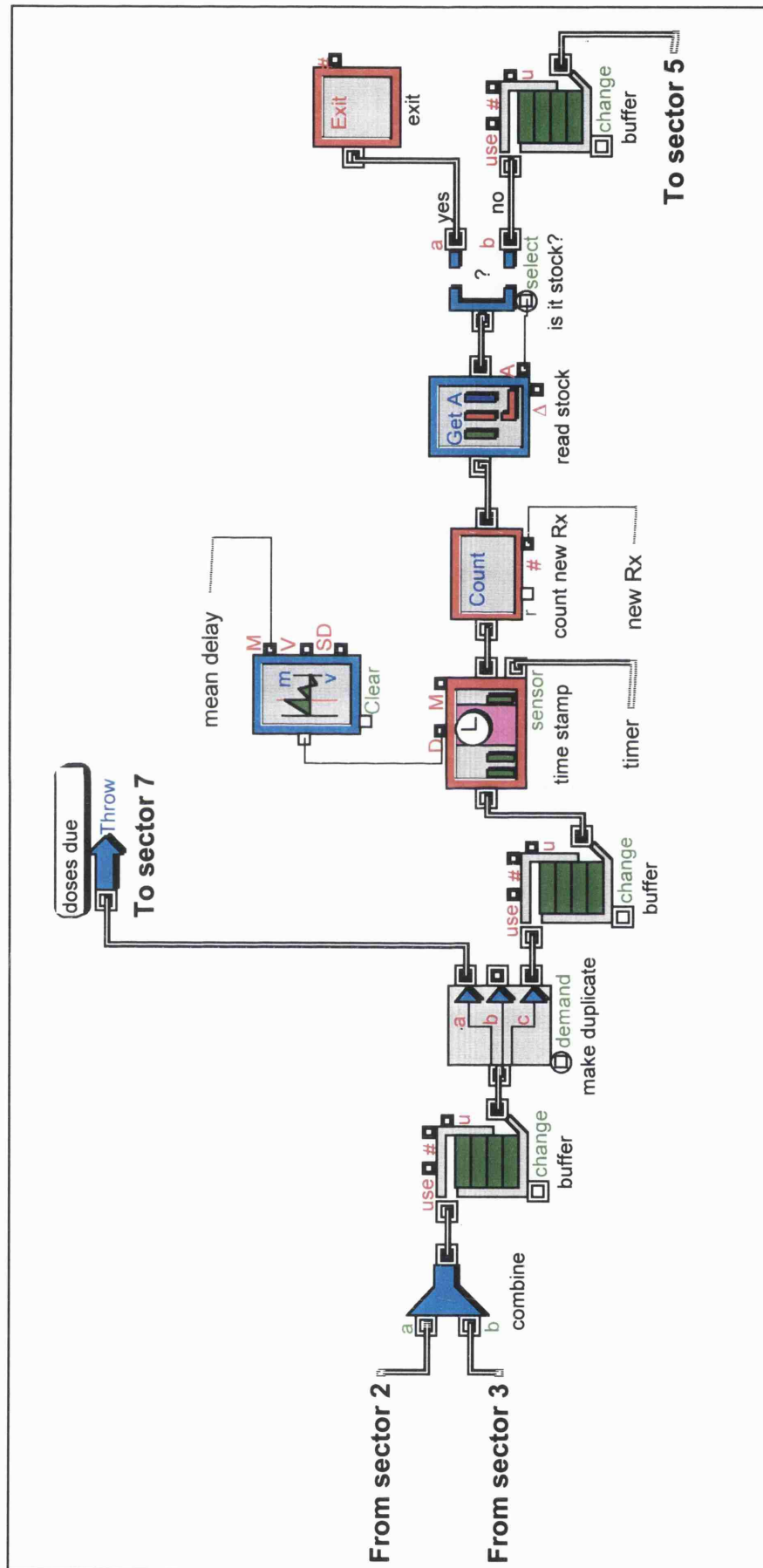


Figure A6.7 Sector 4: Determine whether item is available on ward.

information is transferred to sector 9.

The *get attribute* block 'read stock' reads the attribute STOCK for each medication order item and outputs its value at the 'A' connector. This value is read by the *select discrete event output* block 'is it stock?', which diverts the item via the top output if it is a stock item (STOCK = 1), and via the bottom output if it is a non-stock item (STOCK = 2). Stock items do not have to be supplied and therefore leave the model via the *exit* block 'exit'. Non-stock items continue on to sector 5: 'Delays in supply'.

Sector 5: Delays in supply

This sector represents the delays incurred during the supply of non-stock items; its appearance is shown in figure A6.8.

The *unbatch* block 'make duplicate' creates a duplicate of each item that passes through. One copy of each item is then transferred via the *throw* block 'doses missed' to sector 8, so that the number of doses omitted can be calculated. The second item passes into the 'ward pharmacist' submodel.

'Ward pharmacist' submodel

The on-screen appearance of this submodel is shown in figure A6.9. The *resource* block 'number of items waiting' stores the simulated medication orders as they await the simulated ward pharmacist's visit. The number of items held in this block at any one time is output to the two *set value* blocks 'number of items'.

The times of the morning and afternoon ward pharmacists' visits are determined in the same way. A description of the morning visits follows. Each simulated day on which the ward pharmacist is to make a morning visit to the ward, the *program* block 'morning visit' produces an item at 0:00 hours. This item corresponds to a ward pharmacist. An item is also produced on a Sunday to represent nurses taking drug charts to the pharmacy department. The time at which the pharmacist visits

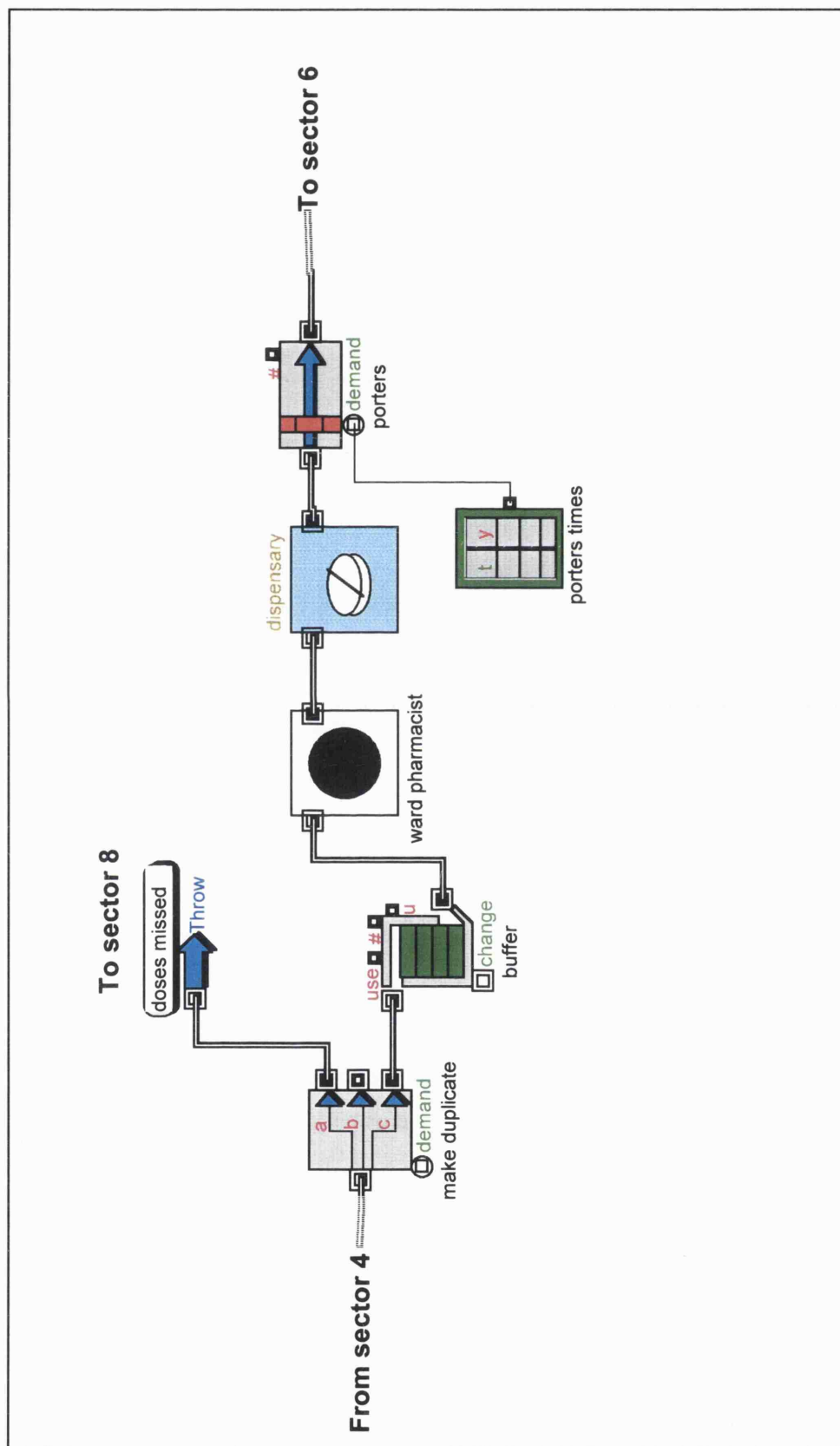


Figure A6.8 Sector 5: Delays in supply.

The functions of the 'ward pharmacist' and 'dispensary' submodels are illustrated in figures A6.9 and A6.10 respectively.

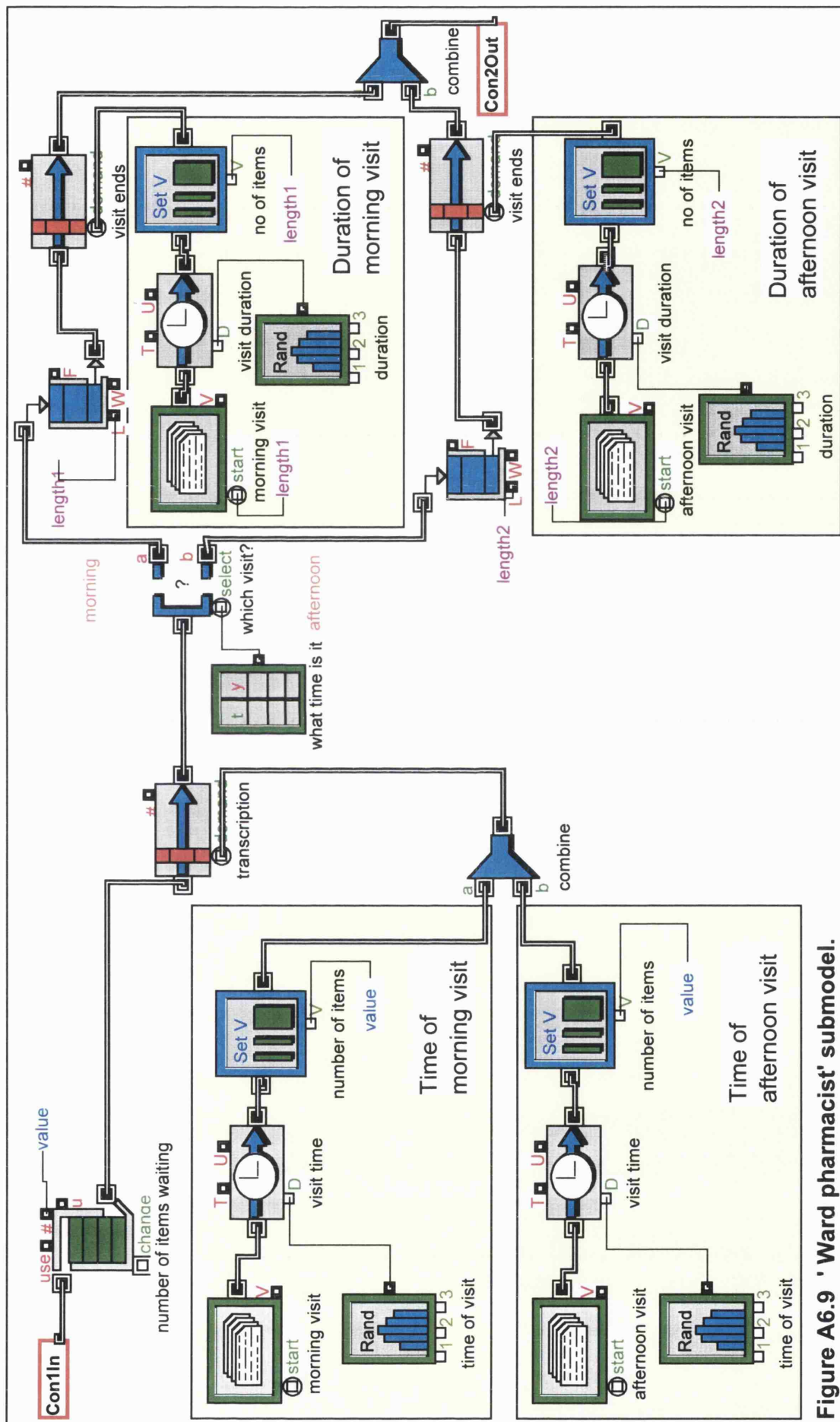


Figure A6.9 'Ward pharmacist' submodel.

the ward is randomly drawn from the distribution of visit times in the *input random number* block 'time of visit' (table A6.9), as determined in section 4.9. The *activity, delay* block 'visit time' reads the time at which the visit is due, and holds the ward pharmacist item until that time. At the scheduled time, the pharmacist item is released and passes on to the *set value* block 'number of items'. This block reads the number of medication orders currently awaiting the ward pharmacist, and gives the ward pharmacist item the corresponding value. The ward pharmacist item then activates the 'demand' connector of the *activity, service* block 'transcription', to indicate that the appropriate number of medication orders can pass through.

The *input data* block 'what time is it?' outputs a value of one between 1 pm and midnight, and zero at all other times. The *select discrete event output* block 'which visit?' diverts items via the top connector if a zero (corresponding to a morning visit) is input at its 'select' connector. If a value of one (corresponding to an afternoon visit) is input then the item is diverted via the bottom connector. Items then pass to the appropriate *queue, first in first out* block while the pharmacist completes his or her duties and returns to the pharmacy department. Whenever one or more items arrive in the *queue, first in first out* block, the *program* block 'morning visit' generates an item representing the return of the pharmacist to the ward. The *activity delay* block 'visit duration' holds this item for the period of time input from the *input random number* block 'duration' (table A6.9), as determined in section 4.9. The item is allocated a value by the *set value* block 'no of items' corresponding to the number of medication orders that have been transcribed and are awaiting the pharmacist's return to the dispensary. When the item arrives at the 'select' connector of the *activity, service* block 'visit ends', the medication orders can enter the 'dispensary' submodel.

Time	Parameter	Surgical ward		Medical ward	
		Mean	Distribution	Mean	Distribution
Morning	Time (hours)	9.91 (9.55 am)	Erlang (9.91, 197)	8.93 (8.56 am)	Erlang (8.93, 650)
	Duration (hours)	0.90	Lognormal (0.90, 0.20)	0.55	Lognormal (0.55, 0.13)
Afternoon	Time (hours)	2.70 (2.42 pm)	Erlang (2.7, 47)	2.46 (2.27 pm)	Erlang (2.46, 45)
	Duration (hours)	0.39	Lognormal (0.39, 0.097)	0.33	Lognormal (0.33, 0.18)

Table A6.9 Times and durations of simulated ward pharmacists' visits.

'Dispensary' submodel

In this submodel (figure A6.10), items initially pass into the *queue*, *first in first out* block 'dispensary'. Whenever one or more items arrives in this queue, the *program* block 'begin dispense' generates a simulation item that represents a member of staff beginning the dispensing process. This item then passes into the *activity, delay* block 'dispense delay' which holds it for a time corresponding to the duration of the dispensing process. The duration of the dispensing process is input from the *input random number* block 'dispensing time'. Dispensing times are represented by the lognormal (0.97, 0.95) distribution, as described in section 4.10. A series of *equation* blocks ensure that all medication orders are dispensed before the pharmacy department closes. The *input data* blocks 'time of day' and 'day of week' convert simulation hours into hours of the twenty-four hour clock and hours of the week, respectively. The *equation* block 'weekdays' reads the time of day, and contains the equation: IF (DISPTIME > (17.4 - TIME) RESULT = (17.5 - TIME); ELSE RESULT = DISPTIME;. Similarly, the *equation* block 'weekends' contains the equation: IF (DISPTIME > (12.5 - TIME) RESULT = (12.4 - TIME); ELSE RESULT = DISPTIME;. This ensures that all items are dispensed just before the department closes. The *equation* block 'which day?' contains the equation: IF (DAYOFWEEK < 120) RESULT = WEEKDAY; ELSE

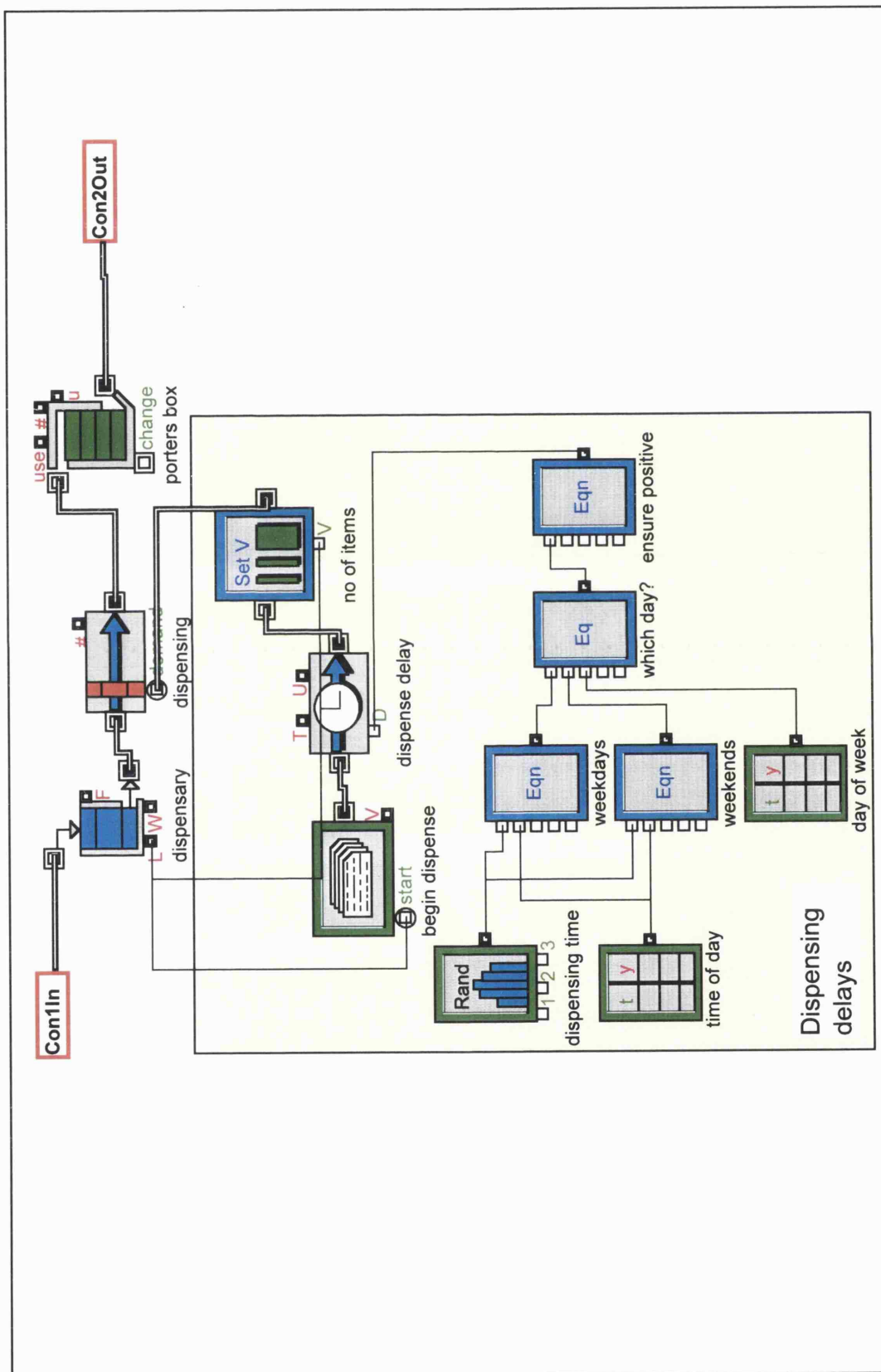


Figure A6.10 'Dispensary' submodel.

RESULT = WEEKEND;,. The equation block 'ensure positive' contains the equation: IF (INPUT<0) RESULT = 0; ELSE RESULT = INPUT;.

The *set value* block 'no of items' sets the value of the 'dispensary staff' simulation item to the number of medication order items awaiting dispensing. This item then activates the 'select' connector of the *activity, service* block 'dispensing', to indicate that dispensing has been completed. The simulated medication order items are then allowed to pass into the *resource* block 'porter's box' to await delivery to the ward.

Once simulation items have passed through the 'ward pharmacist' and 'dispensary' submodels, they represent medication orders that have been dispensed and can be delivered to the ward. The *activity, service* block 'porters' allows simulation items to pass through only when a value of one is detected at its 'select' connector. The *input data* block 'porters' times' outputs a value of one at the times of the porters' visits and a zero at all other times. Porters' deliveries are scheduled for noon, 2 pm, 3:30 pm and 5:30 pm during the week and at 12:30 pm on Saturdays. An additional 'porters visit' is also scheduled for the time at which the pharmacy department closes on each day, to represent nurses who are asked to collect any items remaining in the department at closing time.

Sector 6: Return of dispensed items to the ward

This sector represents the delivery of dispensed medication orders to the ward by the porters. Its on-screen appearance is shown in figure A6.11. The *activity, multiple* block '30 minute delay' delays all simulation items for a period of half an hour, representing the time taken for the porters to reach the ward. Supplied medication orders are then transferred via the *throw* block 'supplied item' to sector 8.

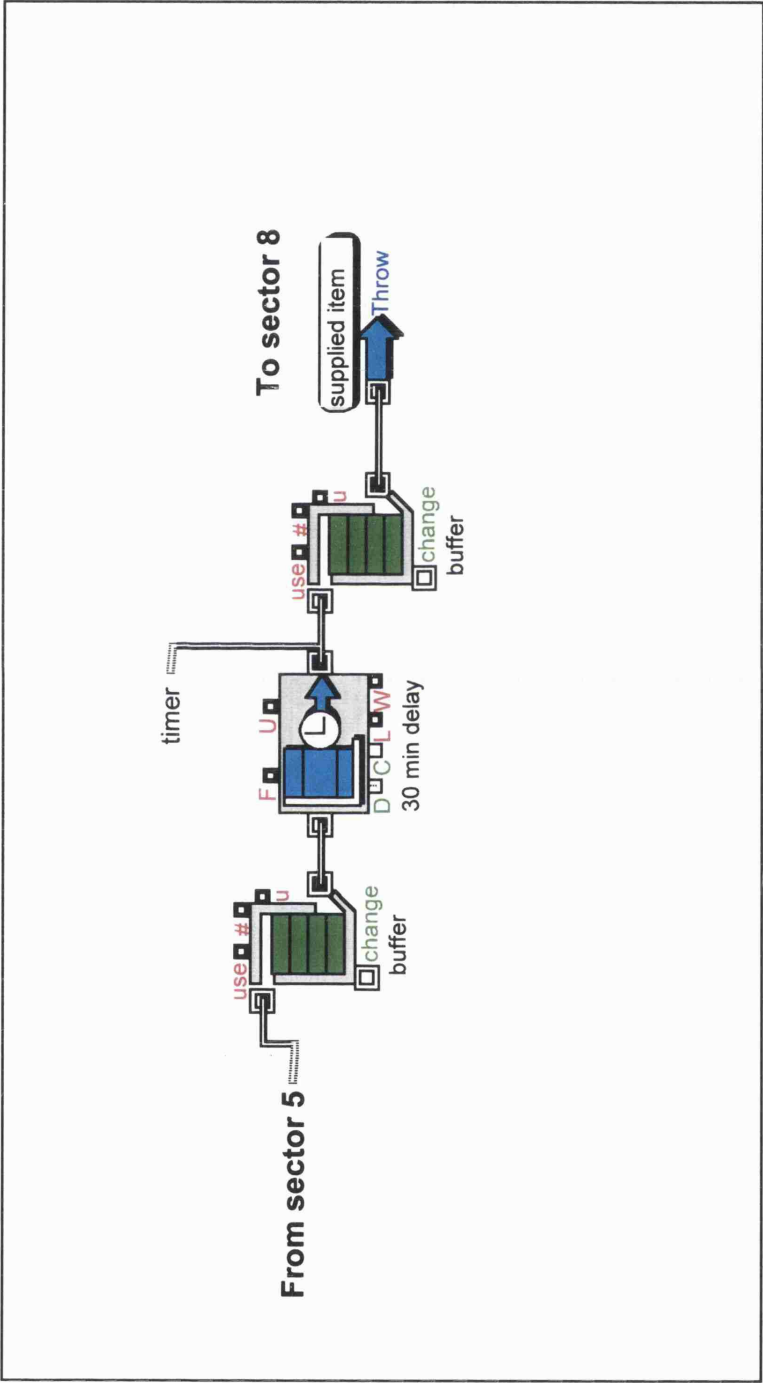


Figure A6.11 Sector 6: Return of dispensed items to the ward.

Sector 7: Calculate number of doses due

This sector simulates the administration of doses during scheduled drug rounds and counts the number of doses that should be administered. It is illustrated in figure A6.12.

Items representing prescribed medication orders arrive from sector 4 at the *catch* block 'doses due'. The *select discrete event output (5)* block 'select output' diverts each medication order item to the appropriate drug round submodel, depending on the next drug round scheduled. The *input data* block 'what is the time of the next drug round?' outputs different values according to the current simulation time, to indicate the next drug round that is scheduled.

'6 am round', '12 noon round', '6 pm round' and '10 pm round' submodels

These submodels each represent a different drug round. The four are similar; therefore only the '12 noon round' submodel, illustrated in figure A6.13, will be described here.

Simulated medication order items await the noon drug round in the *resource* block 'await 12 noon'. To represent the discontinuation of medication orders, the *program* block 'discontinuation' generates simulation items with inter-arrival times described by an exponential distribution. No item is produced at time zero. The mean of the exponential distribution is input by the *divide* block 'divide'. The *constant* block 'time between discontinuations' contains the value for the mean time between successive discontinuations per patient, as determined in section 4.5 (297 hours on the surgical ward; 150 on the medical ward). This value is then divided by the current number of patients on the ward and input to the *program* block. Each item produced by the *program* block is given a value of -1, as these represent deductions from the number of current medication orders. Each of these items passes on to the 'change' connector of the *resource* block 'await 12 noon', from which an appropriate number of medication order items are removed.

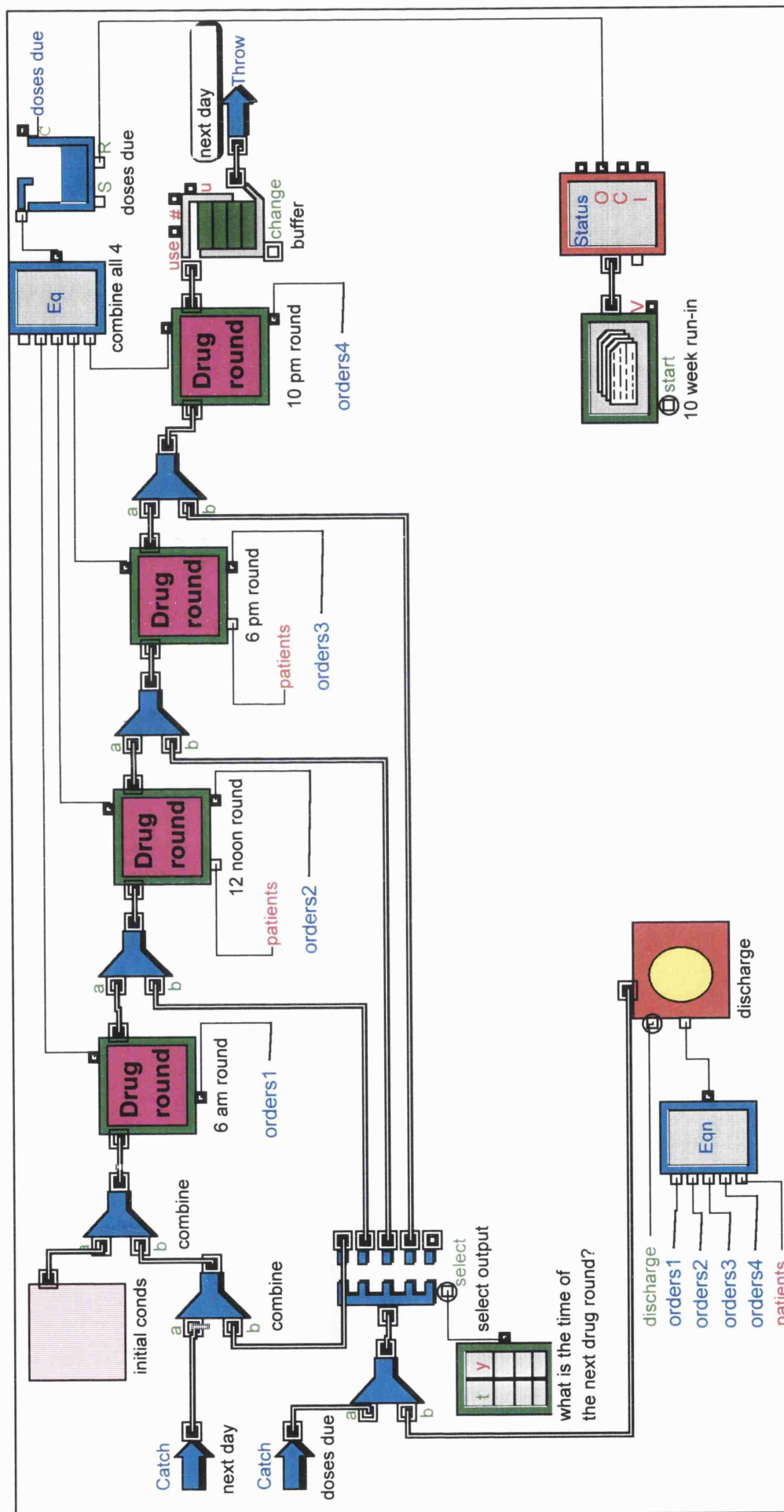


Figure A6.12 Sector 7: Calculate number of doses due.

The functions of the 'drug round', 'discharge' and 'initial conds' submodels are illustrated in figures A6.13, A6.14 and A6.15 respectively.

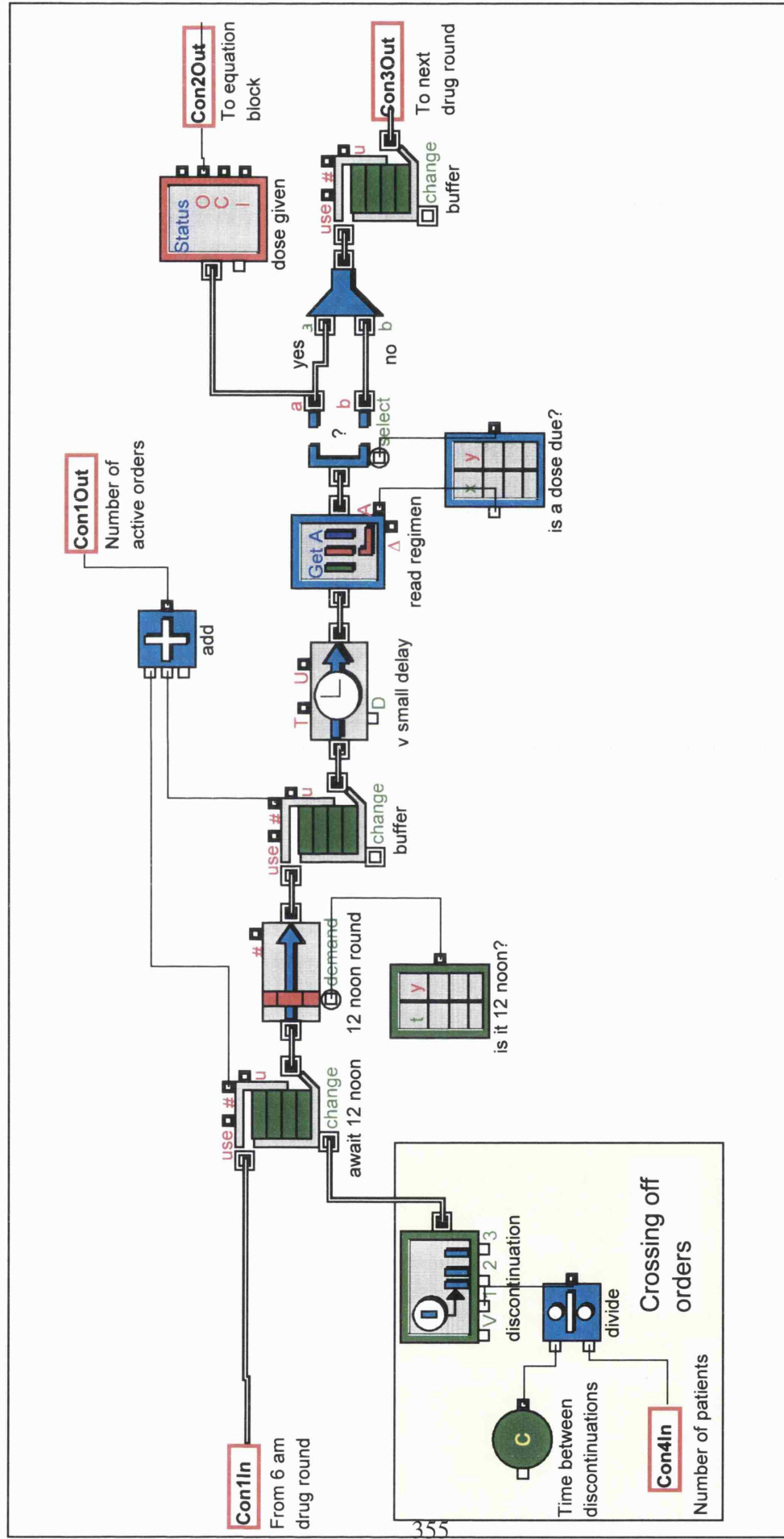


Figure A6.13 '12 noon drug round' submodel.

The *input data* block 'is it 12 noon?' outputs a value of one at noon each simulated day, which activates the 'demand' connector of the *activity, service* block '12 noon round' and allows simulation items to be passed through. The *activity, delay* block 'v small delay' delays each medication order item for thirty simulated seconds, to ensure that items arrive individually at the *status* block later in the submodel. The *get attribute* block 'read regimen' reads the attribute REG and outputs its value to the *conversion table* block 'is a dose due?'. This *conversion table* outputs a zero for the medication orders for which a dose is due, and a value of one for those medication orders for which no dose is due. For example, only medication orders prescribed to be administered 3 or 4 times daily will have doses due at noon. The *select discrete event output* block diverts medication order items through the top output if a dose is due, and through the bottom output otherwise. Medication order items passing through the top output are viewed by the *status* block 'dose given' and a value of one output at its 'O' connector for each item that passes through. The total number of simulation items in this submodel at any one time is output to the 'discharge' submodel. All medication order items then continue through the model to await the 6 pm round.

After the 10 pm drug round has taken place, medication order items are transferred via the *throw* block 'next day' to await the 6 am drug round and the cycle begins again.

The outputs from the *status* blocks in each drug round submodel are added together by the *accumulate* block 'doses due'. The *equation* block 'combine all 4' contains the equation: $RESULT = INPUT1 + INPUT2 + INPUT3 + INPUT4$; The *accumulate* block 'doses due' therefore keeps a cumulative count of all doses that should have been administered. This information is output to sector 9: 'Calculate the omission rate'.

'Discharge' submodel

This submodel (figure A6.14) ensures that whenever a simulated patient is discharged, an appropriate number of medication order items are removed from those active on the ward. This therefore represents the removal of that patient's

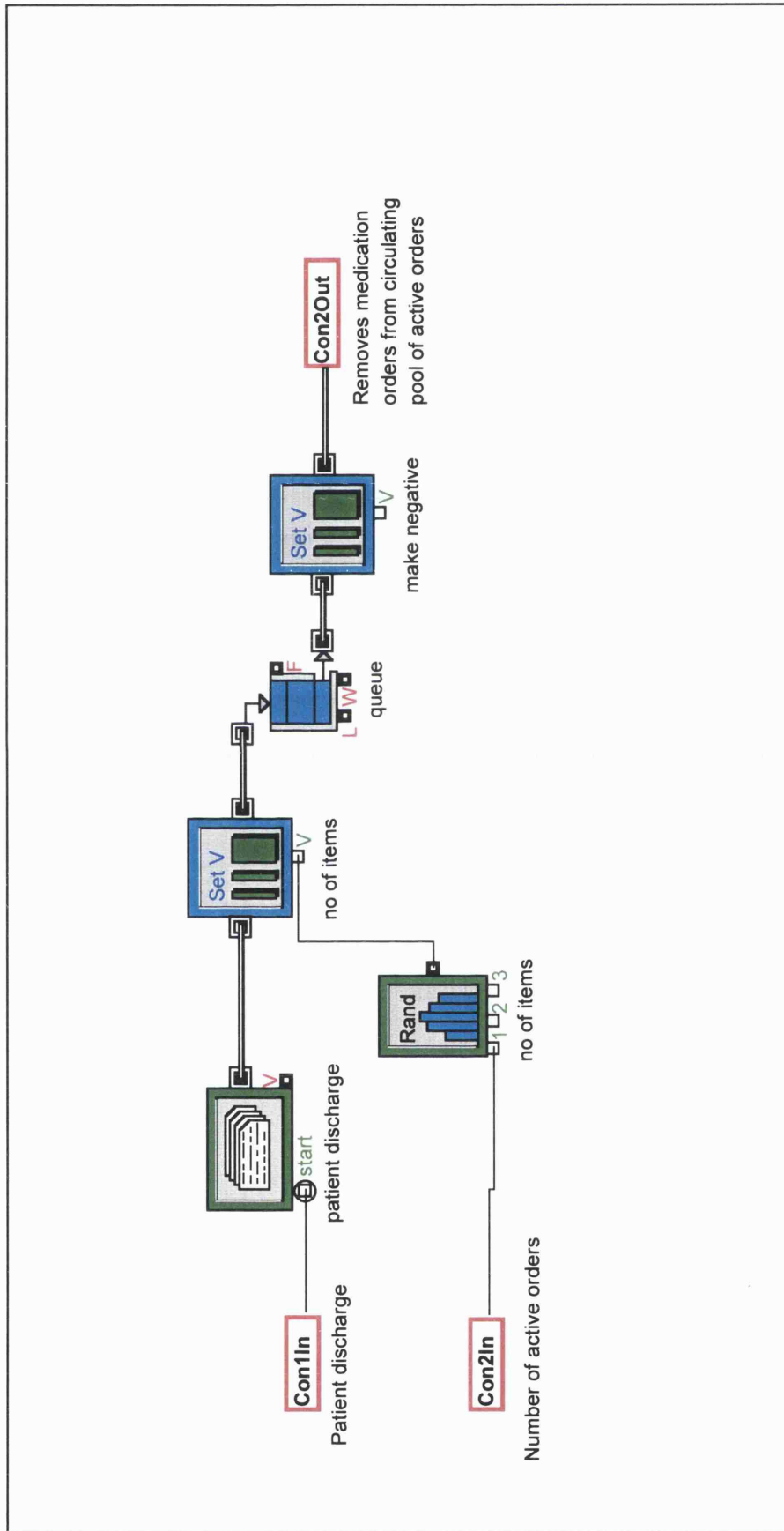


Figure A6.14 'Discharge' submodel.

drug chart from the ward.

A signal is obtained from sector 1 each time a patient is discharged. This triggers the generation of an item by the *program* block 'patient discharge'. The *set value* block 'no of items' gives the item a value equivalent to the number of active medication orders that the simulated patient has at the time of discharge. This information is input by the *input random number* block 'no of items', which outputs random numbers drawn from a Poisson distribution with a mean equal to the average number of medication orders per patient. The average number of medication orders per patient is determined by dividing the total number of active medication orders by the number of patients on the simulated ward. The *equation* block 'make -ve' turns the number calculated into a negative value as these medication orders are to be removed from the pool of active medication orders.

Submodel 'initial conds'

This submodel (figure A6.15) provides an initial number of medication order items to represent those associated with the patients already on the ward when the simulation begins. The *program* block 'initial items' produces five items for every patient present on the surgical ward at the beginning of the simulation, and seven for each patient on the medical ward. The *set attribute* block 'set regimen' sets the dose regime attribute REG for these items, using the overall probabilities for each dose regime obtained during the observation-based study, as described in section 4.5 (table A6.10).

Value of REG	Surgical ward	Medical ward
1	0.46	0.51
2	0.20	0.18
3	0.12	0.22
4	0.22	0.09

Table A6.10 Probabilities of each value of the attribute REG allocated to initial simulated medication orders.

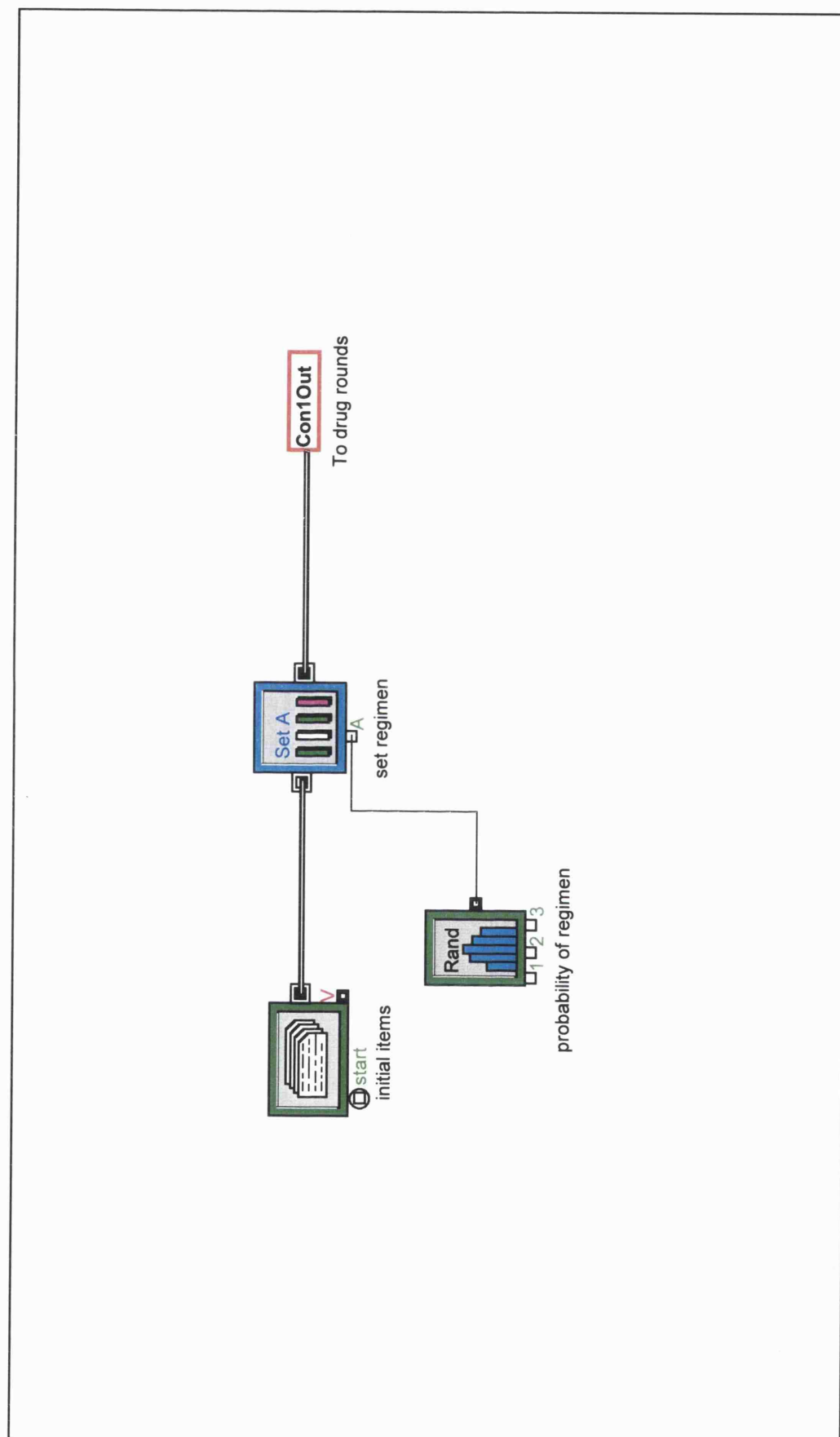


Figure A6.15 'Initial conds' submodel.

Sector 8: Calculate number of doses omitted

This sector calculates the number of doses that are omitted while unavailable medication orders are being supplied. Its appearance is shown in figure A6.16. Much of sector 8 is identical to sector 7.

Medication orders identical to those awaiting supply in sector 5 enter this sector via the *catch* block 'doses missed'. These medication order items then pass through a series of drug rounds and the number of doses missed is calculated in a similar way to that described for sector 7. However, in this case, no medication orders are removed on patient discharge and none are crossed off in between drug rounds. The cumulative number of doses omitted is output to sector 9: 'Calculate the omission rate'.

Whenever a simulated medication order item is supplied in sector 6, an identical item enters sector 8 via the *catch* block 'supplied item'. This item is given a negative value and causes the removal of a medication order item from the pool of circulating unavailable items.

Sector 9: Calculate the U-MAE rate

This sector calculates the percentage U-MAE rate and is shown in figure A6.17.

The cumulative number of doses due is input from sector 7 and the number of doses omitted from sector 8. The *equation* block 'express as %' contains the equation:
$$\text{RESULT} = 100 * ((\text{DOSES MISSED})/(\text{DOSES DUE}));$$
The result is output to the *file out* block 'output results' which is used to store the results from each simulation run. The number of medication orders prescribed and the mean delay time between the prescription of a non-stock drug and its delivery to the ward are also recorded.

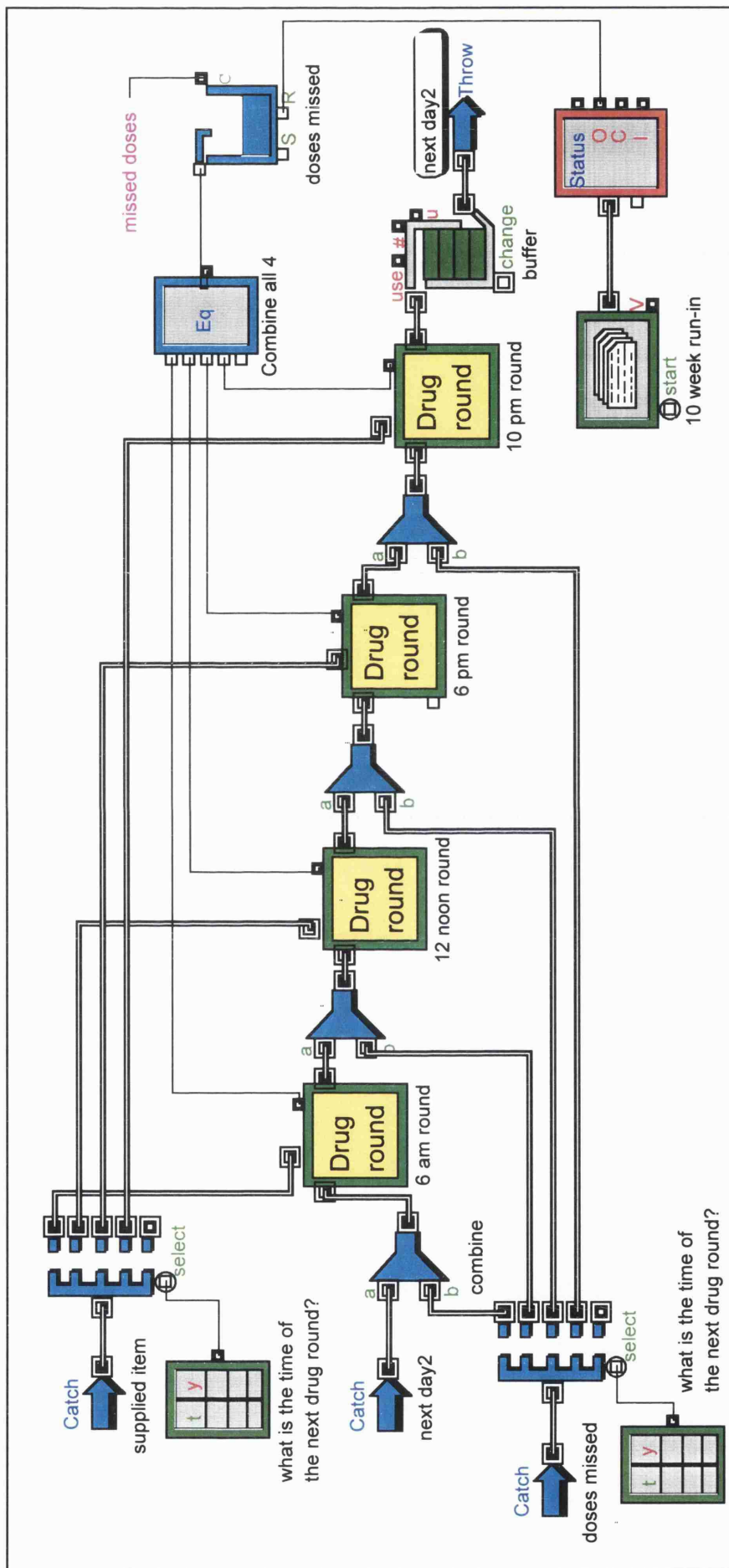


Figure A6.16 Sector 8: Calculate number of doses omitted.

The structure of the 'drug round' submodel was shown in figure A6.13

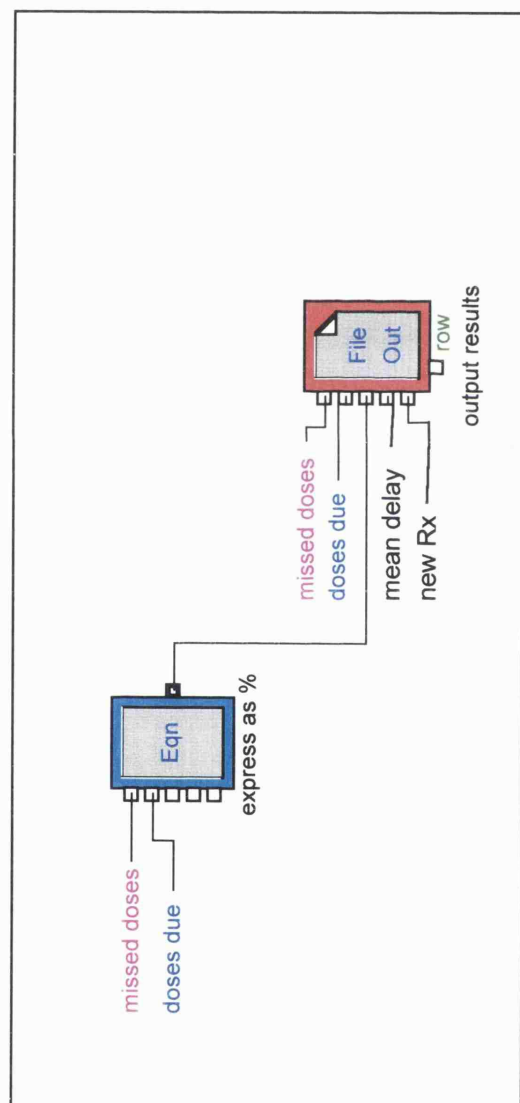


Figure A6.17 Sector 9: Calculate the omission rate.

Appendix 7

Assumptions made during the construction of the final simulation model

Appendix Seven: Assumptions made during the construction of the final simulation model

This appendix lists the assumptions made during the construction of the base case model. General assumptions will first be listed, before other assumptions are considered on a sector-by-sector basis. Model parameters were discussed separately in Chapter Four.

General assumptions

1. Only regularly scheduled medication administered via the oral, inhaled, ocular, aural and nasal routes was included. Drugs prescribed to be given once only, controlled drugs and drugs for administration via the parenteral, topical and rectal routes are not usually administered during scheduled drug rounds and were therefore not included in the model. Drugs prescribed to be given 'when required' were excluded as it is difficult to determine when doses are due and hence when an U-MAE has occurred. The inclusion of all medication orders would have required a more complex model, but because most medication orders on the study wards are for regularly scheduled oral drugs, this would have provided little additional information.
2. The dispensing of medication by the resident pharmacist outside of pharmacy opening hours was not included; this was discussed in section 4.12.
3. It was assumed that from Mondays to Saturdays, ward staff do not take drug charts to the pharmacy department to request the supply of medication. However, it was assumed that on Sunday mornings, nurses take any drug charts with unsupplied non-stock medication orders to the pharmacy department for dispensing (section 4.12).
4. Although weekend pharmacy services were included in the model, bank holidays were excluded.

Sector 1 - Patient admissions and discharges

1. Patient admissions were considered to occur according to a non-stationary Poisson process. This means that admissions were assumed to occur one at a time, independently of one another. However the mean time interval between successive admissions changes with time (section 4.7).
2. If the ward is full, it was assumed that potential admissions are instead admitted to another ward. Patients do not wait for a bed to become empty on the study ward (section 5.3.2).
3. It was assumed that there was no interaction between time of day and day of week with respect to admission rates.

Sector 2 - Medication order writing for newly admitted patients

1. Whenever a patient is admitted to the ward, a number of drugs are prescribed. It was assumed on an *a priori* basis that these are prescribed at the same time, and that the number of drugs prescribed on admission is independent of the time of the patient's arrival.
2. It was assumed that drugs could be prescribed to be given only once, twice, three or four times daily (section 4.6.5.3).
3. It was assumed that all once daily doses were scheduled for 6 am, all twice daily doses for 6 am and 6 pm, all three times daily doses for 6 am, noon and 10 pm and all four times daily doses for 6 am, noon, 6 pm and 10 pm (section 4.6.5.4).
4. It was assumed on an *a priori basis* that there is no relationship between the time of patient admission and any of the following: the probability of drugs being ward stock, the probability of drugs having been taken by the patient prior to their admission, and the probability of drugs being prescribed in each dose regimen (once, twice, three or four times daily).

Sector 3 - Medication order writing for existing patients

1. Medication orders were considered to be written according to a non-stationary Poisson process. This means that they were assumed to occur one at a time,

independently of one another. However the mean time interval between successive medication orders changes with time (section 4.5.5.3).

2. The number of medication orders written varies with the number of patients on the ward.
3. It was assumed on an *a priori basis* that there is no relationship between the time of medication order writing and any of the following: the probability of drugs being ward stock, the probability of drugs having been taken by the patient prior to their admission, and the probability of drugs being prescribed in each dose regimen (once, twice, three or four times daily).
4. As above, it was assumed that drugs could be prescribed to be given only once, twice, three or four times daily (section 4.6.5.3).
5. As above, it was assumed that all once daily doses were scheduled for 6 am, all twice daily doses for 6 am and 6 pm, all three times daily doses for 6 am, noon and 10 pm and all four times daily doses for 6 am, noon, 6 pm and 10 pm (section 4.6.5.4).
6. It was assumed that there was no interaction between time of day and day of week with respect to the frequency of medication order writing on weekdays.

Sector 4 - Determine whether item is available on the ward.

1. It was assumed that drugs that are ward stock are always available for administration.
2. It was assumed that all previously dispensed non-stock drugs are also available.

Sector 5 - Delays in supply

1. Non-stock drugs cannot be dispensed until after the next scheduled ward pharmacist's visit.
2. Each pharmacist visits only one ward (the same one each weekday).
3. No data were available concerning the times and durations of Saturday morning

ward visits. It was therefore assumed that Saturday visits have a similar time and a similar duration to weekday morning visits. Pharmacists do not inspect each patient's drug chart on Saturdays and the time spent on each ward is therefore much less than during the week. However, weekend staffing arrangements mean that there is usually only one pharmacist for each hospital wing; the time taken to visit every ward in a hospital wing was considered to be similar to the time taken to inspect all the drug charts on one ward during a weekday morning visit.

4. It was assumed that the ward pharmacist would transcribe details of every unsupplied medication order immediately after his or her arrival on the ward, and that he or she is aware of every unsupplied order. Any medication orders written during the remainder of the pharmacists's visit would therefore not be transcribed until the next visit. This assumption was considered appropriate as medical staff do not generally draw pharmacists' or nurses' attention to newly written medication orders.
5. At each ward visit, all medication order items that require dispensing are transcribed onto one ward pharmacy order form. All items on each order form are then dispensed and checked together in the pharmacy department. This reflects standard practice at the study hospital.
6. It was assumed that all medication is available in the pharmacy department and can be dispensed.
7. Dispensing and checking are represented as one process; the different stages of the dispensing and checking processes are not considered individually.
8. It was assumed that during weekdays, the mean dispensing time remains constant throughout the morning and first part of the afternoon. However, it was also assumed that all items are dispensed before the pharmacy department closes each day; in the model, dispensing times therefore decline in a linear fashion as the closing time approaches.
9. No data were available concerning weekend dispensing times. It was therefore

assumed that these were the same as during weekdays. This assumption is unlikely to affect the model's results as it was assumed that all medication orders are dispensed before the department closes.

10. It was assumed that nurses do not take drug charts to the pharmacy department for dispensing between Mondays and Fridays, and that the resident pharmacist is not called (section 4.12.3). However, it was assumed that on Sunday mornings, drug charts with any unsupplied medication orders would be taken to the pharmacy for dispensing.
11. Inpatient dispensing was assumed to occur independently of outpatient dispensing and is therefore unaffected by factors such as outpatient workload.

Sector 6 - Return of dispensed items to the ward

1. It was assumed that any items remaining in the pharmacy department at closing time would be collected by a nurse from the ward concerned. This reflects standard practice in the study hospital.
2. Once the porters' box containing dispensed items arrives on the ward, the items are immediately available for administration; the time required to unpack the box is considered to be negligible.
3. Because the last daily porters' delivery arrives during the 6 pm drug round, it was assumed that any 6 pm doses supplied in that delivery would be administered in 50% of cases.

Sector 7 - Calculate number of doses due

1. It was assumed that all once daily doses are given at 6 am; all twice daily doses at 6 am and 6 pm; all three times daily doses at 6 am, noon and 10 pm, and all four times daily doses at 6 am, noon, 6 pm and 10 pm (section 4.6.5.4).
2. It was assumed that the drug rounds occur at the times for which they are scheduled (6 am, noon, 6 pm and 10 pm).
3. It was also assumed that all the doses prescribed are to be administered; the effects

of patients being 'nil-by-mouth' and other contraindications to medication administration were considered to be negligible.

4. It was assumed that no drugs are prescribed to be administered less than once daily or more than four times daily (section 4.6.5.3).

Sector 8 - Calculate number of doses omitted

1. Drugs are never discontinued by the prescriber before they have been supplied by the pharmacy department.
2. Patients are never discharged before medication has been supplied.
3. It was assumed that in accordance with hospital policy, drugs are not obtained from other wards, from patients' own supplies or from other patients' supplies.
4. It was assumed that if doses are unavailable at the time of the drug round, the doses concerned are not given at a later time. In practice, doses omitted due to unavailability are sometimes given during a later drug round if the drug subsequently becomes available. However the effect of this practice was considered to be negligible.

Appendix 8

Model verification

Appendix Eight: Model verification

This appendix describes in detail the measures taken to verify that the simulation model was behaving as intended.

During the verification process, it was confirmed that all model logic was working as expected and that all data generated by the model had the characteristics desired. Where appropriate, data output by the model were compared to real world data using chi square tests. Whenever chi square tests were carried out, the number of intervals in which the data were presented were selected so that each cell contained an expected number of at least five and so that cells were approximately equiprobable (Law and Kelton, 1991).

Verification will be described on a sector-by-sector basis, giving the methods and results pertaining to each sector. During each verification run, the first ten weeks of data were discarded before collecting any simulation results.

Sector 1 - Patient admissions and discharges

Methods

Simulated patients' admission times and lengths of stay were recorded during a four-month verification run, using an Extend *information* block. Admission times were classified according to time of day and day of week, and compared to real world data. Values for the mean length of stay, the mean number of simulated patients admitted each week and the mean midnight bed occupancy were obtained from the model and compared to real world values. It was also confirmed that the number of simulated patients on the ward did not exceed the number of beds and that the data output to sectors 2, 3 and 7 were those intended.

Results

There was no significant difference between the times of the simulated admissions and the times of the real world admissions for either ward (table A8.1).

Time period	Surgical ward			Medical ward		
	Real world (n = 36)	Model output (n = 280)	p value (χ^2 test)	Real world (n = 26)	Model output (n = 299)	p value (χ^2 test)
00:00 to 16:00	10 (28%)	75 (27%)	0.99	8 (31%)	90 (30%)	0.97
16:00 to 18:00	12 (33%)	94 (34%)		7 (27%)	75 (25%)	
18:00 to 00:00	14 (39%)	111 (39%)		11 (42%)	134 (45%)	

Table A8.1 Time periods during which patients admitted.

For the surgical ward, there was no difference in the days of the week on which simulated and real world patients were admitted. However, for the medical ward, significant differences in days of admission were identified (table A8.2). This was considered to be due to the assumption made in section 4.7.5.2 that numbers of patients admitted to this ward each day from Monday to Friday were equal.

The data output to sectors 2, 3 and 7 was confirmed to be that intended. Table A8.3 shows the results for other verification parameters that were considered.

Day	Surgical ward			Medical ward		
	Real world (n = 1059)	Model output (n = 280)	p value (χ^2 test)	Real world (n = 586)	Model output (n = 299)	p value (χ^2 test)
Mon	177 (17%)	46 (16%)	0.60	97 (17%)	43 (14%)	0.02
Tues	184 (17%)	42 (15%)		123 (21%)	51 (17%)	
Wed	166 (16%)	39 (14%)		73 (12%)	28 (9%)	
Thur	179 (17%)	48 (17%)		98 (17%)	40 (13%)	
Fri	101 (9%)	28 (10%)		108 (18%)	71 (24%)	
Sat	62 (6%)	13 (5%)		52 (9%)	34 (11%)	
Sun	190 (18%)	64 (23%)		35 (6%)	32 (11%)	

Table A8.2 Days of the week on which patients admitted.

Parameter	Surgical ward		Medical ward	
	Real world (n = 1059)	Model output (n = 280)	Real world (n = 586)	Model output (n = 308)
Mean length of stay	9.2 nights	8.8 nights	6.7 nights	6.7 nights
Mean number of patients admitted each week	19.9	20.0	13.2	12.1
Mean midnight bed occupancy	91%	89%	84%	78%
Maximum number of patients on ward	28	28	16	16

Table A8.3 Other verification parameters relating to sector 1 of the model.

Sector 2 - Medication order writing for newly admitted patients

Methods

It was confirmed that a simulation item was generated in this sector of the model each time a simulated new admission occurred in sector 1. The attributes STOCK, PRIOR and REG were recorded for the first 500 simulated medication orders produced and compared to the characteristics of the real world sample. The number of medication orders allocated to each simulated new admission was also calculated and compared to real world data.

Results

A simulation item was produced in this sector each time a simulated patient was admitted in sector 1; other results are summarised in tables A8.4 - A8.6.

Characteristic	Surgical ward			Medical ward		
	Real world (n = 111)	Model output (n = 500)	p value (χ^2 test)	Real world (n = 139)	Model output (n = 500)	p value (χ^2 test)
Medication orders for stock drugs	62 (56%)	285 (57%)	0.91	41 (29%)	135 (27%)	0.52
Medication orders for drugs taken prior to admission	103 (93%)	460 (92%)	0.93	118 (85%)	420 (84%)	0.92

Table A8.4 Characteristics of medication orders written for newly admitted patients.

Number of daily doses	Surgical ward			Medical ward		
	Real world (n = 111)	Model output (n = 500)	p value (χ^2 test)	Real world (n = 139)	Model output (n = 500)	p value (χ^2 test)
One	67 (60%)	275 (55%)	0.77	79 (57%)	296 (59%)	0.75
Two	22 (20%)	110 (22%)		24 (17%)	94 (19%)	
Three	7 (6%)	40 (8%)		29 (21%)	90 (18%)	
Four	15 (14%)	75 (15%)		7 (5%)	20 (4%)	

Table A8.5 Dose regimes of medication orders written for newly admitted patients.

Medication orders	Surgical ward			Medical ward		
	Real world (n = 38)	Model output (n = 141)	p value (χ^2 test)	Real world (n = 28)	Model output (n = 90)	p value (χ^2 test)
0	8 (21%)	26 (18%)	0.77	3 (11%)	5 (6%)	0.09
1	6 (16%)	22 (16%)		3 (11%)	6 (7%)	
2	4 (10%)	21 (15%)		2 (7%)	16 (18%)	
3	6 (16%)	24 (17%)		3 (11%)	11 (12%)	
4	5 (13%)	21 (15%)		0 (0%)	13 (14%)	
5	3 (8%)	9 (6%)		5 (18%)	5 (6%)	
6	1 (3%)	9 (6%)		4 (14%)	10 (11%)	
7	3 (8%)	5 (4%)		0 (0%)	6 (7%)	
8	1 (3%)	3 (2%)		4 (14%)	5 (6%)	
≥ 9	1 (3%)	1 (1%)		4 (14%)	13 (14%)	
Mean	2.9	3.5		5.0	4.7	

Table A8.6 Medication orders written for each new admission.

Sector 3 - Medication order writing for existing patients

Methods

The mean number of simulated medication orders generated each week was determined for a one hundred week simulation run and compared with real world data. The attributes of the first 500 items generated during a verification run were recorded and compared with data from the real world. The mean medication order inter-arrival time was also examined, to verify that it varied according to the number of patients on the ward, the time of day and the day of week.

Results

For the surgical ward, the mean number of simulated medication orders generated per week was 45.6, in the real world this figure was also 45.6. For the medical ward, these figures were 37.5 and 36.1 respectively.

Inter-arrival times between simulated medication orders were found to vary appropriately according to the time of day, day of week and number of patients on the ward. The other parameters examined are summarised in tables A8.7 - A8.10.

Parameter	Surgical ward			Medical ward		
	Real world (n = 92)	Model output (n = 500)	p value (χ^2 test)	Real world (n = 75)	Model output (n = 500)	p value (χ^2 test)
Medication orders for stock drugs	78 (85%)	435 (87%)	0.68	38 (51%)	257 (51%)	0.99
Medication orders for drugs taken prior to admission	7 (8%)	40 (8%)	0.93	3 (4%)	38 (8%)	0.77

Table A8.7 Characteristics of medication orders written for existing patients.

Number of daily doses	Surgical ward			Medical ward		
	Real world (n = 92)	Model output (n = 500)	p value (χ^2 test)	Real world (n = 75)	Model output (n = 500)	p value (χ^2 test)
One	27 (29%)	160 (32%)	0.89	28 (37%)	209 (42%)	0.83
Two	17 (18%)	100 (20%)		16 (21%)	99 (20%)	
Three	18 (20%)	95 (19%)		18 (24%)	122 (24%)	
Four	30 (33%)	145 (29%)		13 (18%)	70 (14%)	

Table A8.8 Dose regimes of medication orders written for existing patients.

Time interval	Surgical ward			Medical ward		
	Real world (n = 80)	Model output (n = 500)	p value (χ^2 test)	Real world (n = 67)	Model output (n = 500)	p value (χ^2 test)
00:00 to 12:00	29 (36%)	177 (35%)	0.96	25 (37%)	196 (39%)	0.95
12:00 to 20:00	46 (58%)	284 (57%)		37 (55%)	270 (54%)	
20:00 to 00:00	5 (6%)	39 (8%)		5 (7%)	34 (7%)	

Table A8.9 Time periods during which medication orders written for existing patients.

Day	Surgical ward			Medical ward		
	Real world (n = 92)	Model output (n = 500)	p value (χ^2 test)	Real world (n = 75)	Model output (n = 500)	p value (χ^2 test)
Mon	9 (10%)	90 (18%)	0.28	12 (16%)	74 (15%)	0.26
Tues	13 (14%)	95 (19%)		7 (9%)	99 (20%)	
Wed	22 (24%)	104 (21%)		16 (21%)	87 (17%)	
Thur	19 (21%)	84 (17%)		16 (21%)	78 (16%)	
Fri	28 (30%)	116 (23%)		16 (21%)	94 (19%)	
Sat & Sun	1 (1%)	11 (2%)		8 (11%)	68 (14%)	

Table A8.10 Days of the week on which medication orders written for existing patients.

Sector 4 - Determine whether item is available on ward.

Methods

The attribute STOCK was recorded for the first 500 items that exited the model and the first 500 items transferred to sector 5.

Results

Only stock items (STOCK = 1) exited the model, and all non-stock items (STOCK = 2) continued on to sector 5 as desired.

Sector 5 - Delays in supply

Methods

The number of simulation items held in the *resource* block 'items waiting' (inside the submodel 'ward pharmacist') was plotted to confirm that items were being held in this block until the simulated ward pharmacist's visit. Similarly, the number of items in the *queue, first in first out* block 'dispensary' was plotted to ensure that items did not enter the *resource* block 'porters box' until the completion of dispensing. The number of items being dispensed at each point in time was also plotted, to confirm that all simulated medication orders were dispensed before the pharmacy department closed and that none were dispensed after this time. The number of items in the *resource* block 'porters' box' was plotted during a verification run, to ensure that all simulation items were moved to the next stage of the model at the appropriate times and that no items remained in the simulated porter's box overnight.

Results

Items were found to be held in the appropriate blocks until the times of the simulated ward pharmacists' visits and the completion of dispensing. Examination of graphical output confirmed that medication order items were dispensed only during pharmacy opening hours, and that all items were dispensed before the department closed.

Sector 6 - Return of dispensed items to the ward

Methods

The attribute REG was recorded using *information* blocks for the first 500 items that were returned to the simulated ward in this sector and the first 500 simulation items produced in sector 8: 'Calculate number of doses omitted'.

Results

It was confirmed that a corresponding simulation item was produced in sector 8 for every medication order item supplied to the ward in sector 6, as desired.

Sector 7 - Calculate number of doses due

Methods

During a verification run, the times at which simulated medication orders entered each drug round submodel were recorded using *information* blocks. The number of active medication orders circulating through the drug round blocks was also plotted during a three month run of the model and compared to real world data. In order to verify that the calculation of the number of doses given occurred as intended, this sector of the model was also run using simplified inputs for which the number of doses due could be calculated by hand.

Results

Simulated medication orders were passed to appropriate drug rounds according to the time of day. It was also confirmed that whenever patients were discharged from the simulated ward, medication orders were removed from the simulation. There was a mean number of 112 (range 79 to 155) medication orders active on the surgical ward and 98 (50 to 171) on the medical ward, numbers that were considered reasonable with respect to the real world. The number of active medication orders did not rise or fall significantly during model runs of three months. The model output for the number of doses due corresponded to the figures calculated by hand.

Sector 8 - Calculate number of doses omitted

Methods

In a similar manner to that described for sector 7, the times at which medication order items entered each submodel block were recorded using *information* blocks and this sector of the model was run using simplified inputs for which the number of doses omitted could be calculated by hand.

Results

Medication order items were passed to the drug round submodels as appropriate for the time of day, and the model's output for the number of doses omitted matched the figures calculated by hand.

Sector 9 - Calculate the omission rate

Methods

The percentage omission rate was calculated by hand and compared to the model output for five model runs.

Results

It was confirmed that the percentage omission rate was calculated correctly in the model.

Appendix 9

Results of sensitivity analysis

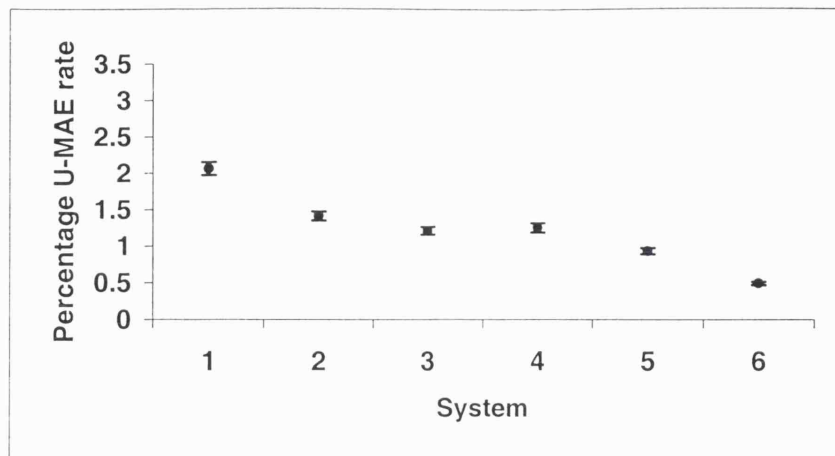
Appendix Nine: Results of sensitivity analyses

This appendix shows the results of the sensitivity analysis that was carried out to assess the relative benefits of six different drug distribution systems, using different values for the model's inputs.

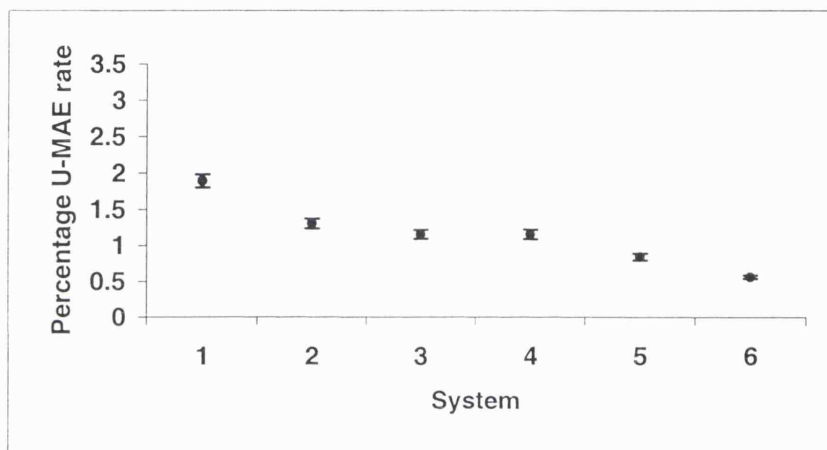
In the figures overleaf, the numbers given refer to the following drug distribution systems, which are described in more detail in Chapter Five:

1. Traditional ward pharmacy system
2. Medication order writing at pre-admission clinics
3. Use of patients' own drugs during their hospital stay
4. Electronic prescribing
5. Extend pharmacy opening hours
6. Extend the residency service

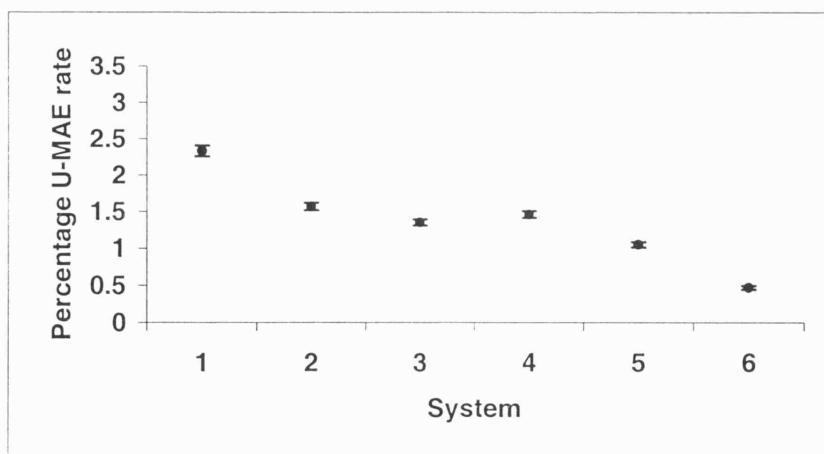
The error bars give the 95% confidence intervals.



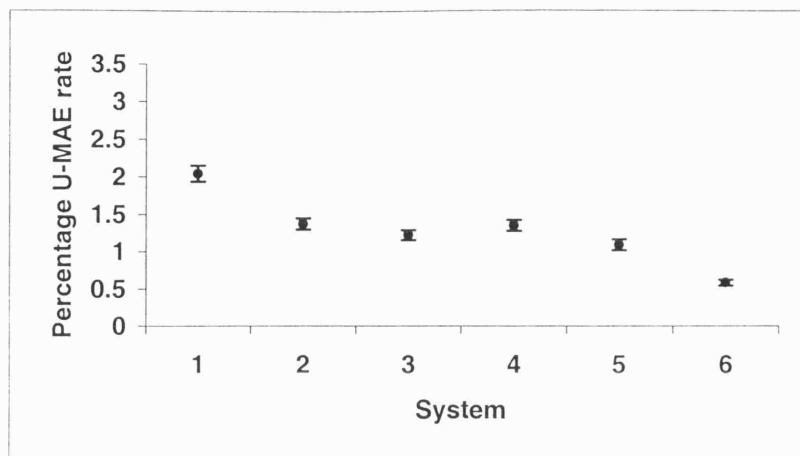
Surgical ward base case



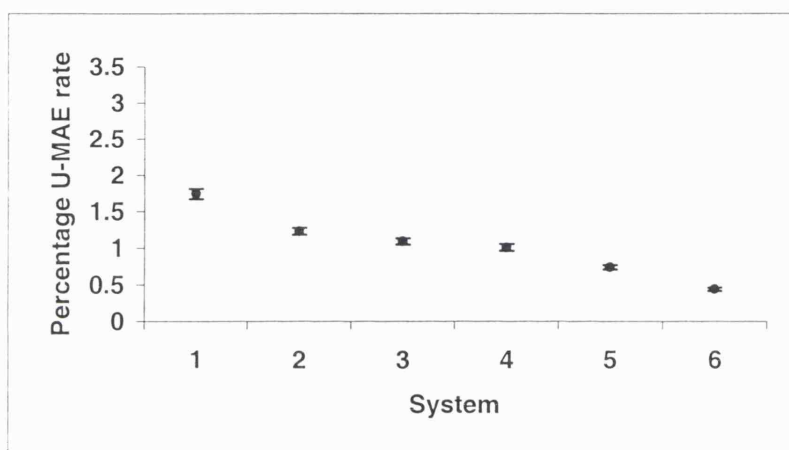
Surgical ward with mean length of stay one day longer



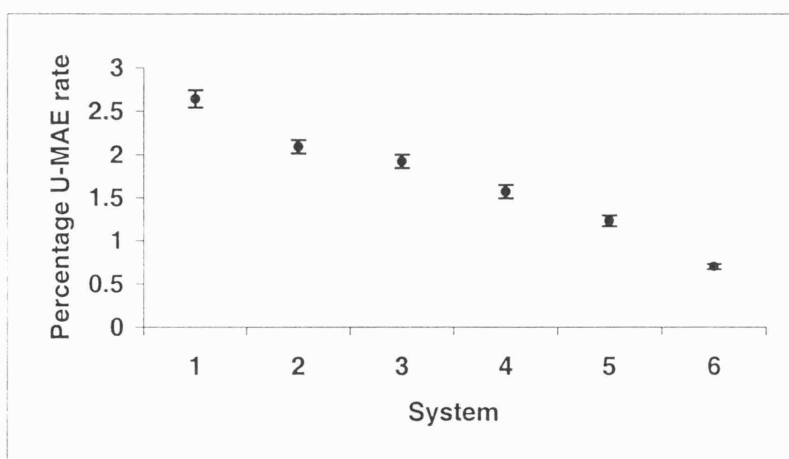
Surgical ward with mean length of stay one day shorter



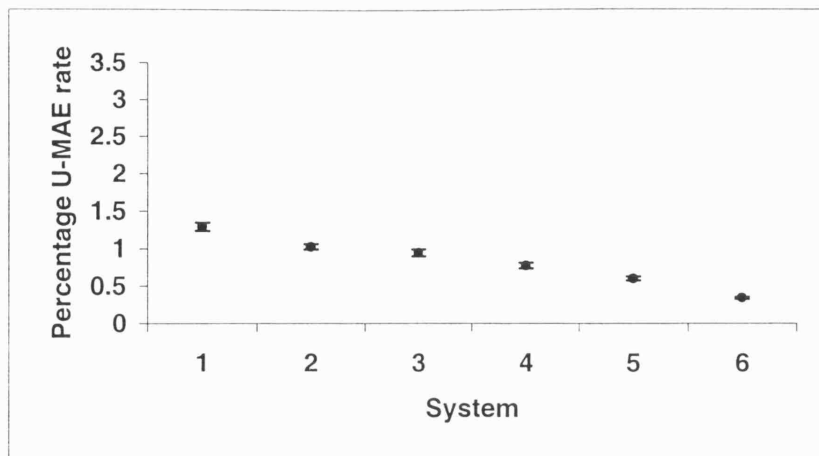
Surgical ward with medical admission times



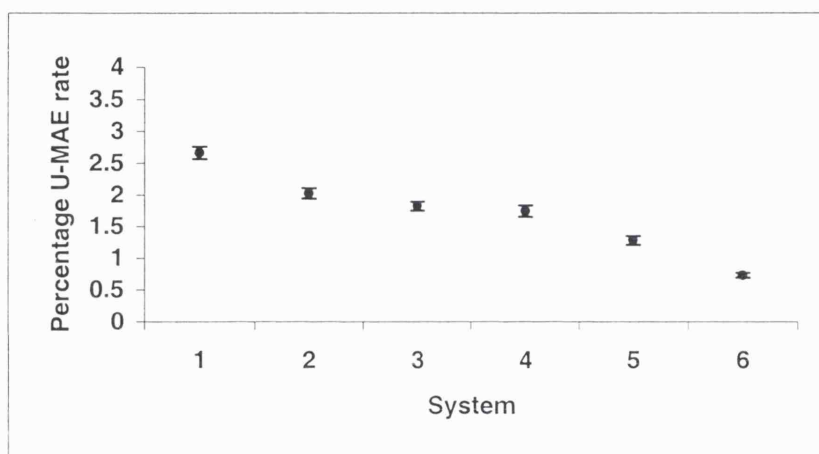
Surgical ward with medical times of medication order writing in existing patients



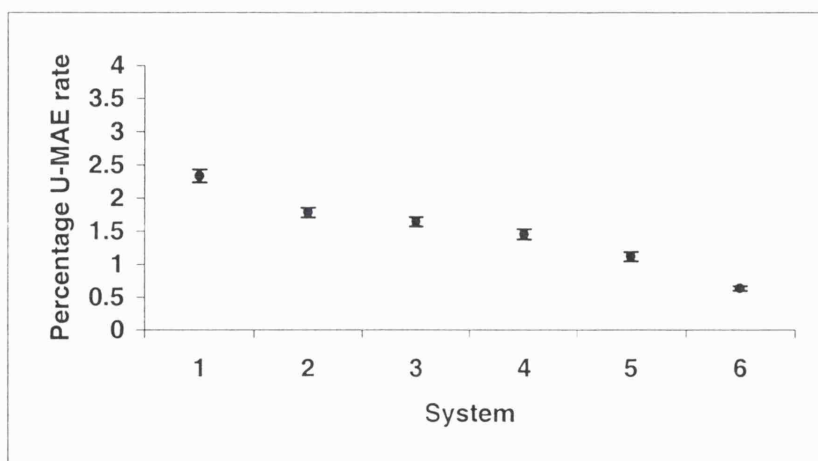
Surgical ward with 60% stock



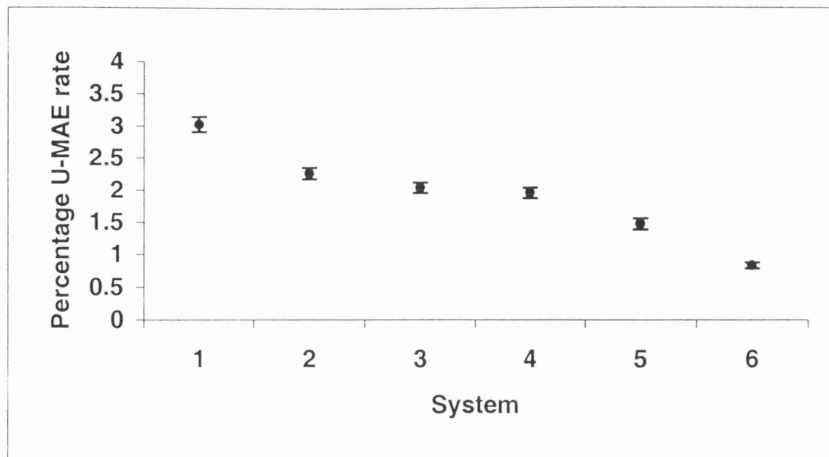
Surgical ward with 80% stock



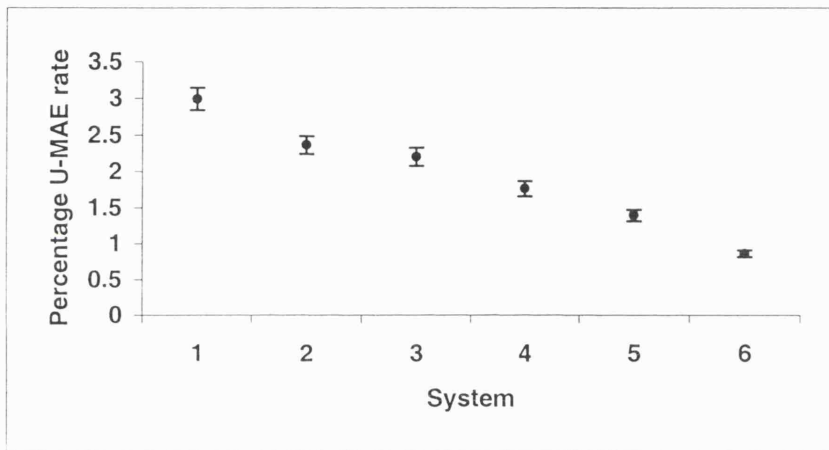
Medical ward base case



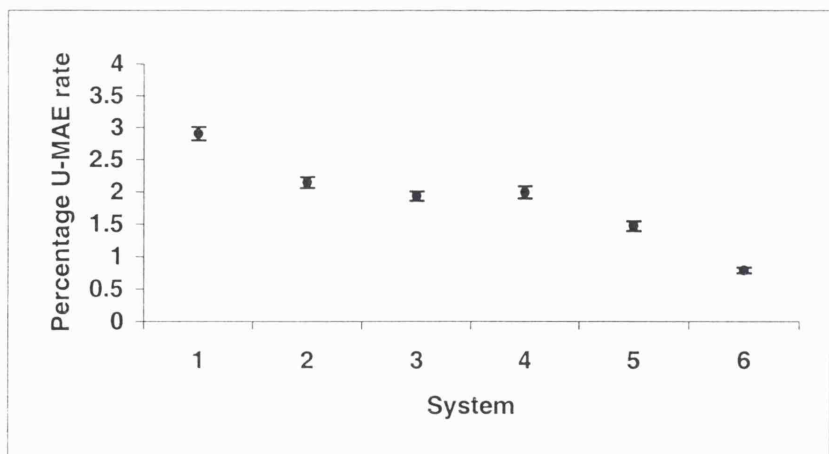
Medical ward with mean length of stay one day longer



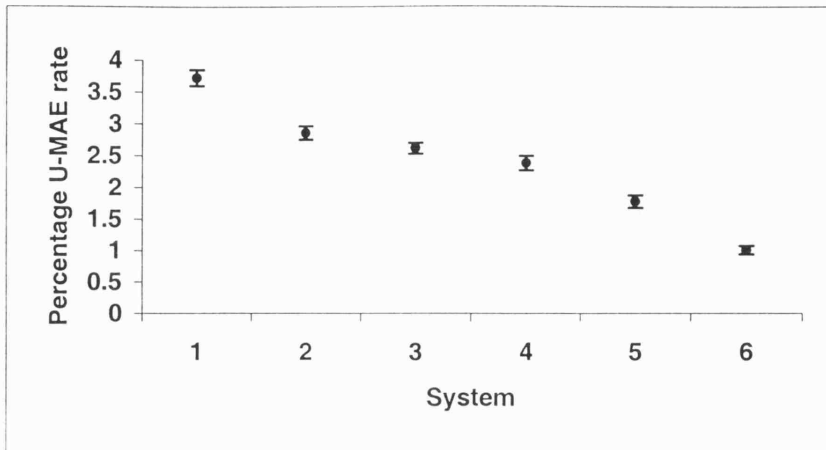
Medical ward with mean length of stay one day shorter



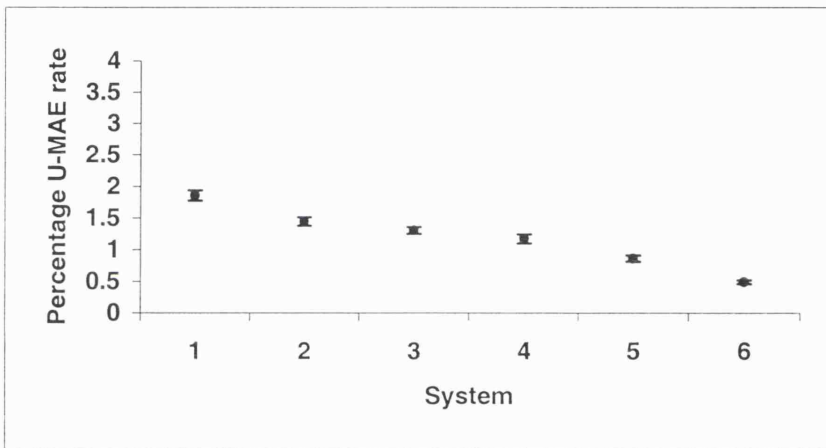
Medical ward with surgical distribution of medication orders on admission



Medical ward with surgical times of medication order writing in existing patients



Medical ward with 60% stock



Medical ward with 80% stock

Appendix 10

**The development of an objective method for assessing
the severity of medication administration errors**

Appendix Ten: The development of an objective method for assessing the severity of medication administration errors

This appendix describes the development of an instrument for objectively scoring the severity of medication administration errors (MAEs). It was envisaged that such an instrument would consist of multiple items, each of which addressed a different aspect of MAE severity.

Objectives

1. To identify objective indicators of MAE severity.
2. To use these to develop an MAE severity assessment instrument.
3. To assess the validity and reliability of the instrument developed.
4. To decide whether the instrument developed could be used to assess the severity of the MAEs identified in the present study.

Methods

Development of the objective severity assessment instrument took place in several stages. The first stage involved the choice of an appropriate criterion measure with which to develop and validate the new instrument. The second stage involved the generation of a pool of objective items for potential use. The third stage was the selection and weighting of suitable items from this pool; finally the new instrument was assessed in terms of validity and reliability.

Selection of criterion scores

An appropriate criterion measure was required with which to develop and validate the

new instrument. As discussed in Chapter Eight, there is no widely accepted method for assessing MAE severity. It was therefore decided to use as a criterion measure the mean subjective severity scores of a group of experienced health care professionals. The methods used to obtain thirty health care professionals' scores for 49 MAEs were described in section 8.4. However, to maximise the validity of the criterion scores, it was decided to exclude those health care professionals who exhibited low test-retest reliability. Test-retest reliability was assessed for each judge using an intraclass correlation coefficient (ICC) (Armitage and Berry, 1994) and the mean score for each MAE calculated after excluding those judges with an ICC below 0.60. The resulting mean values were considered the criterion scores with which to develop and validate the new instrument.

Generation of items for potential inclusion in the new instrument

Two sources were used: interviews with senior health care professionals and a literature search.

Interviews

Semi-structured interviews were conducted with a convenience sample of two senior nurses, two senior physicians and seven senior hospital pharmacists. The nurses and physicians were all from the same teaching hospital; the seven pharmacists were from six different institutions. These interviews explored how the severity of MAEs was perceived to vary and the factors that were considered to be related to MAE severity. The following open-ended questions were used; these were first piloted with two pharmacists.

1. What do you think are the possible consequences of medication administration errors?
(*Prompt: What effects might you expect to see on the patient?*)
2. What would you consider to be a serious error?
3. What would you consider to be a trivial error?
4. If you were asked to differentiate between more significant and less significant

errors, what factors would you consider to be important?

(Prompts: Think of a particularly serious medication error. What was it that made it serious? Think about a less serious medication error. What was it that made it not so serious?)

5. Why are these factors important?
6. If I asked you to judge the significance of a medication error, what sort of information would you need?
(Prompts: Some people might want to know about the patient's reason for admission, their medical history, or their full drug history, what do you think?)
7. Would you consider the financial impact to the hospital?
(Prompts: Do you think it is possible that medication errors could result in extra costs to the hospital? Is this important?)
8. Is there anything else that you think may be relevant?

Interviews were taped and transcribed, then common themes identified.

Analysis of the literature

Existing research was reviewed to identify objective indicators of MAE severity suggested or used previously.

Selection of items and their weights

Suitable items were selected from the pool generated and appropriate response categories developed. Each of the 49 MAE cases for which criterion scores existed was then scored using each item. Pearson's correlation coefficient was computed for each pair of items to identify any multi-collinearity; a coefficient below 0.8 was considered to represent a relationship free from multi-collinearity (Bryman and Cramer, 1997). A stratified sample of 25 of the 49 MAE cases was then selected, where the cases were stratified according to the responses for each item. These 25 cases were used in the development of the new instrument, the remaining 24 were reserved for its validation.

Multiple regression analyses were carried out using the 25 selected cases to identify those items that were most closely related to the criterion scores. A constant was not used in the regression as it was considered desirable that the regression line should pass through the origin. The unstandardised regression coefficients were used as the item weights in the final instrument (Perloff and Persons, 1988). Two pharmacists were asked to check the wording of each item included in the final instrument to ensure that it was clear and unambiguous, and to comment on the face validity of the items included. Cronbach's alpha¹ was also calculated for the final instrument, using all 49 cases.

Reliability and validity of the new instrument

Reliability

Two pharmacists used the new instrument to assess 136 MAEs identified during a previous observation-based study (Taxis, 1997); the agreement between them was assessed using Pearson's correlation coefficient. The scores obtained using the new instrument can be considered to be ordinal in nature. However, it has been suggested that ordinal scales containing more than about seven points assume interval properties (Bryman and Cramer, 1997). It has also been suggested that Pearson's correlation coefficient can be used with any ordinal data (Labovitz, 1970), provided these data do not have a highly skewed distribution (O'Brien, 1979). Pearson's correlation coefficient was therefore selected for use.

Validity

The agreement between the scores obtained using the new instrument and the criterion scores for the 24 validation cases was assessed using Pearson's correlation coefficient.

The scores obtained for the MAEs with known outcomes were also calculated and compared with the severity of those outcomes, in the same manner as that described in Chapter Eight.

¹

Cronbach's alpha is a measure of internal consistency; it gives an indication of the extent to which scores for each item are correlated with the scores for other items and the total scale score.

Results

Selection of criterion scores

Test-retest intraclass correlation coefficients (ICCs) could be calculated for twenty-eight of the thirty health care professionals; two doctors did not return a second set of scores. ICCs ranged from 0.34 to 0.98 (median 0.80). Five of the twenty-eight had ICCs less than 0.60; these were all nurses. It was decided to include the scores of the two doctors who did not return the second set of scores, as the doctors as a group had high test-retest ICCs. The scores from twenty-five health care professionals were therefore used to calculate the criterion scores, which had a median of 4.5 and ranged from 0.8 to 9.6.

Generation of items for potential inclusion in the new instrument

Interviews

The health care professionals interviewed suggested many factors that they perceived to be related to the severity of MAEs (table A10.1).

The clinical state of the patient prior to the occurrence of an error was considered important by many of the interviewees, a medication error in a critically ill patient being considered more serious than the same error in a stable patient. Actual patient outcome and potential patient outcome were perceived to be two separate issues. The interviewees considered actual outcome to be related to the specific effects on the patient concerned whereas potential outcome took into account the effects possible in the patient group as a whole. With respect to the route of administration, the respondents implied that errors in drugs given via the intravenous route were more serious than those in drugs given via other routes.

Factor	Number of responses
The underlying clinical status of the patient concerned	7
Actual patient outcome	6
Potential patient outcome	6
Extent to which procedures were not followed	6
Pharmacology of the drug involved	4
Significance of the system failure	3
Route of administration of the drug involved	2
The degree of any medical intervention needed	2
The extent to which the patient is aware of the error	2
Number of medication errors occurring	2
Likelihood of litigation	1
Magnitude of any increased length of stay	1
Magnitude of any discrepancy in dose	1

Table A10.1 Factors that would be taken into account by health care professionals (n=11) when assessing the severity of MAEs.

Analysis of the literature

Items included in existing objective assessment instruments were summarised in Chapter Seven (table 7.2). Two other studies have specifically explored factors related to MAE severity. First, in a UK district general hospital, seventeen nurse managers were sent a questionnaire asking which criteria they used when assessing the severity of medication errors (Gladstone, 1995). Twelve questionnaires were returned. A wide range of factors were suggested, although the published report does not specify whether open-ended or closed questions were used. As well as type of error and type of drug, respondents apparently took into account the real or potential effect on the patient, the pace of work on the ward, staffing conditions and the nurse's reaction to the error. However, these latter factors may relate more to nurses' professional conduct than to the risk of patient harm following an MAE.

In the second study, Wolf *et al* (1996a) attempted to identify the factors associated with a

perceived harmful outcome from medication errors. In this study, nurses were asked to describe a medication error with which they had been involved, then indicate its severity on both a four-point Likert scale and a visual analogue scale. A multiple regression analysis was performed using the 94 respondents, to determine which factors were most highly correlated with perceived severity. Factors investigated included the phase of the drug distribution system in which the error occurred, the categories of person responsible for the error and the resulting treatment needed by the patient. However, the factors investigated within each of these categories were neither mutually exclusive nor exhaustive, and omission errors were apparently excluded. It was found that errors necessitating patient transfer or additional medication were associated with high severity scores, as were errors for which a physician was responsible. There were some anomalies in the results that are not explained in the paper. For example, errors occurring in the dispensing phase of the drug distribution system were found to be associated with high perceived severity scores, whereas errors for which a pharmacist was responsible were associated with low scores. Since pharmacists must have been responsible for many of the dispensing errors this result is difficult to explain. The results are also limited by the fact that severity was judged solely by the nurse involved.

Selection of items and their weights

Of the items identified, only some were considered suitable for inclusion in the new instrument. The underlying clinical status of the patient had to be excluded as this information was not available for the majority of the fifty cases for which criterion scores existed. Patient outcomes may not be known in observation-based studies and therefore could not be included. Objective indicators of the drug's pharmacology are its therapeutic index and its legal classification; items reflecting each were included. Route of administration and the number of times the same MAE was repeated in the same patient were also included in initial tests. Although the magnitude of any discrepancy in dose is an objective measure, the inclusion of this item would have produced a scale that was biased against wrong dose errors. It was decided to instead use an item relating to whether the MAE resulted in a drug being used outside the recommendations in its data

sheet. This would give a measure of the extent of the discrepancy for wrong dose errors, and also would be applicable to other types of error. The items included in the multiple regression analyses were therefore as follows:

- NUMBER: Number of identical MAEs repeated in the same patient.
(One = 0; two or three = 1; four or more = 2)
- CLASS: Legal classification of the product concerned ¹.
(GSL = 0; P = 1; POM = 2)
- ROUTE: Route of administration of the drug concerned.
(topical = 0; oral = 1; parenteral = 2)
- SIZE: Whether the error resulted in a drug being used outside its data sheet recommendations.
(no = 0; yes = 1)
- THERAPEUTIC INDEX: Therapeutic index of the drug concerned ².
(high = 0; low = 1).

The scores allocated to each response category of NUMBER, CLASS and ROUTE make implicit assumptions about the relative severity of the different responses. For example, there is an assumption that an error involving a parenteral drug is twice as severe as one involving an oral drug. These assumptions were tested using regression analyses in which each response category was tested separately and their unstandardised regression weights compared. It was concluded that the assumptions made regarding the relative severities of each response category were reasonable.

There was no evidence of multi-collinearity (Pearson's correlation coefficients between

¹

The classification of a medicinal product relates to how it can be obtained by the general public. A substance listed in the general sales list (GSL) can be sold from any retail outlet. A substance that is a pharmacy medicine (P) can only be sold to the public from a registered pharmacy, under the supervision of a pharmacist. A substance listed in the Medicines (Prescription Only) Order (POM) can only be supplied against a valid prescription from a medical practitioner.

²

The therapeutic index of a drug relates to the ratio of the therapeutic dose to the toxic dose. If a drug has a low therapeutic index, the toxic dose is not much greater than the therapeutic dose.

pairs of items ranged from 0.14 to 0.65). The results of the multiple regression analyses are summarised in table A10.2 and suggest that the best predictor of the criterion scores was model 2, which included the variables THERAPEUTIC INDEX, SIZE, NUMBER and CLASS. The unstandardised regression coefficients (table A10.3) were used as the item weights; these were adjusted so that the items had integer scores. The final instrument (figure A10.1) showed good correlation with the criterion scores for the 25 cases (adjusted $R^2 = 0.93$). Face validity of the final instrument was considered high by the pharmacist assessors. Cronbach's alpha for the final instrument was 0.003.

Model	Details of regression	Variables included in final model*	R^2	R^2_{adj}	SE [†]
1	Forwards stepwise regression, p value to add variable = 0.051	THERAPEUTIC INDEX, SIZE, ROUTE	0.93	0.91	1.69
2	Backwards stepwise regression, p value to remove variable = 0.05	NUMBER, THERAPEUTIC INDEX, SIZE, CLASS	0.94	0.93	1.47
3	Backwards stepwise regression, p value to remove variable = 0.10	NUMBER, THERAPEUTIC INDEX, SIZE, CLASS, ROUTE	0.95	0.93	1.47

Table A10.2 Summary of the results of the multiple regression analyses, showing the three regression models that were the best predictors of the criterion scores.

* Variables are defined in the text.

† SE: Standard error of the estimate.

Variable	Unstandardised regression coefficient
CLASS	1.53
THERAPEUTIC INDEX	2.27
SIZE	2.73
NUMBER	1.16

Table A10.3 Unstandardised regression coefficients for regression model 2.

Assessing the severity of medication administration errors

Instructions

This scoring instrument is designed to assess the severity of medication administration errors. Where a series of identical medication administration errors occur in the same patient, the series should be considered as one case. For each case, complete each of the four items below. Add the four scores to give an overall total. If the total score for one error is more than 100, consider the score to be 100. If two or more drugs are involved (for example if one drug is administered instead of another), then for each item, consider the drug that gives the highest score. A score below 35 indicates a minor error; a score above 35 suggests that the outcome would be moderate or severe.

- | | | |
|--|-----|------|
| 1. What is the legal classification of the drug involved? | GSL | (0) |
| Reference: Medicines, Ethics and Practice Guide: July 1998 | P | (15) |
| Consider any unlicensed medication to be POM and
all herbal/homeopathic remedies to be GSL. | POM | (30) |
| 2. Is the drug involved any one of the following? | No | (0) |
| Digoxin, theophylline/aminophylline, phenytoin, cytotoxics,
carbamazepine, vancomycin (IV), aminoglycosides (IV or IM),
cyclosporin, lithium, morphine, potassium (IV), warfarin, heparin,
insulin, tacrolimus. | Yes | (23) |
| 3. Does the incident result in a drug being used outside of the
recommendations in its data sheet? | No | (0) |
| This includes contra-indications but excludes administration
beyond the expiry date. | Yes | (27) |
| 4. How many identical medication errors occurred together in the same
patient? | 1 | (0) |
| | 2-3 | (12) |
| | ≥4 | (24) |

Figure A10.1 The objective scoring instrument developed.

Reliability and validity of the new instrument

Reliability

The two pharmacists agreed on the scoring of all 136 cases assessed. Pearson's correlation coefficient was therefore 1.00.

Validity

For the 24 validation cases, the correlation between the criterion scores and the scores obtained using the new scale was relatively high ($R^2 = 0.60$; Pearson's correlation coefficient). This figure is not directly comparable with the values quoted in table A10.2 as the regression analyses were via the origin. Figure A10.2 shows a scatter diagram of the objective scores against the criterion scores for all 49 MAE cases.

When the scores for the MAE cases with known outcomes were examined, there was some overlap in the scores for the 'moderate' and 'severe' cases, as shown in figure A10.3. This figure suggests that a score below 35 represents an error likely to be associated with a 'minor' outcome and a score above 35 an error likely to be associated with a 'moderate' or 'severe' outcome.

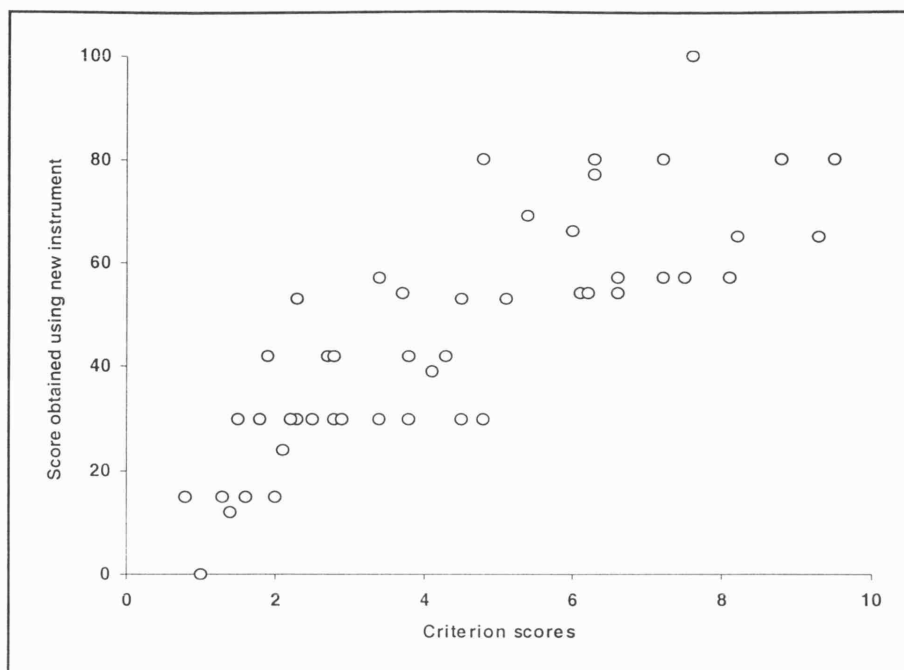


Figure A10.2 Scatter diagram of scores obtained using the objective scoring instrument and the criterion scores ($n = 49$; $R^2 = 0.67$).

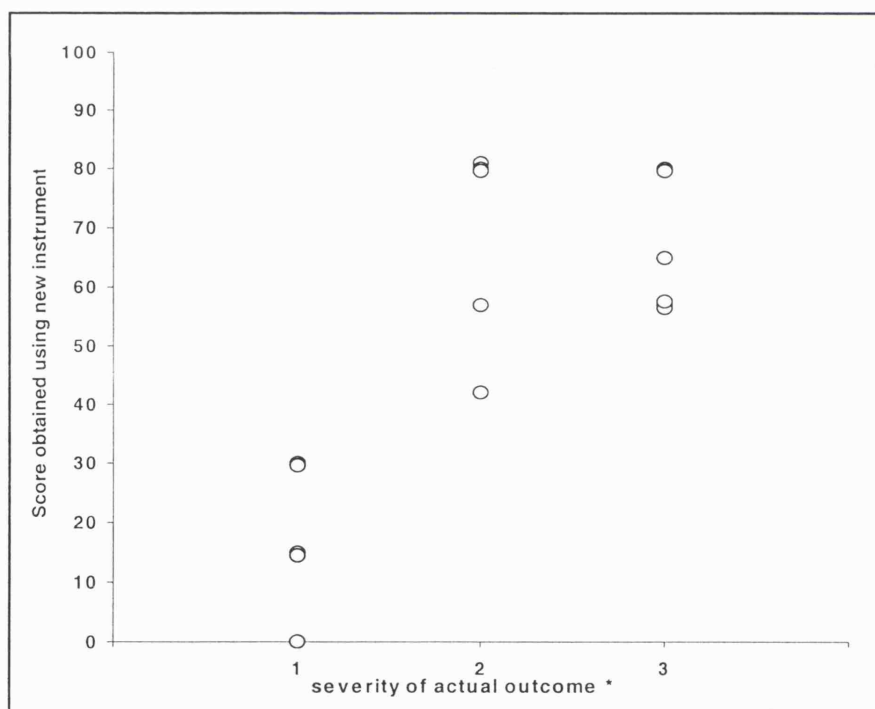


Figure A10.3: Scores obtained using the objective scoring instrument for the MAE's with known outcomes.

* 1 = minor; 2 = moderate; 3 = severe (as defined in section 8.4.2).

Discussion

An instrument for assessing MAE severity was developed, based on proxy indicators of severity. This has been subjected to more extensive testing of validity and reliability than existing instruments of this type (Cobb, 1986b; Rasic *et al*, 1989; Tyndall and Carlson, 1990; Walters *et al*, 1992; Mee *et al*, 1995).

A set of criterion scores was used with which to select the items for inclusion in the new instrument and to determine their relative weights; the choice of criterion measure will therefore affect the results obtained. In the present study, the subjective scores of a group of experienced health care professionals were used as the criterion measure. An alternative approach would have been to use the MAE cases with known outcomes with which to calibrate the new scale; however it may have been difficult to obtain a sufficiently large sample. Excluding those health care professionals who exhibited low test-retest reliability should have increased the validity of the criterion scores used. It could be argued that the two doctors whose test-retest reliability was unknown should also have been excluded. The mean MAE severity scores were therefore recalculated excluding these doctors' scores; differences in the calculated mean scores were very minor and it is unlikely that the decision to include these individuals would have affected the results obtained.

The items selected for inclusion in the scale were designed to be objective. The legal classification of the drug involved was considered to be one such objective item. However, many drugs are currently undergoing changes in legal classification. Many previously prescription-only products have recently been classified as pharmacy medicines, and a smaller number of pharmacy medicines have been reclassified as prescription-only. If this trend continues, the scale may need to be recalibrated.

It was decided not to include an item relating to the clinical state of the patient prior to the MAE's occurrence. This was because this information was not available for many of the cases used during the scale's development. However, severity assessment methods that

do not take into account the patient's condition have been criticised (Davis, 1994) and the inclusion of such an item might increase the validity of the present scale.

Although scores obtained using the new instrument were highly correlated with the criterion scores, the scores for the MAEs with known outcomes did not adequately reflect the severity of those outcomes. This limits the instrument's utility, as moderate and severe errors cannot be distinguished. The addition of one subjective item, relating to the perceived likelihood of significant major clinical effects, was therefore considered. It was found that the inclusion of such an item increased the validity of the scores obtained. The correlation between the criterion scores and the objective scores for the 24 validation cases increased (R^2 increased from 0.60 to 0.68) and moderate and severe cases could then be distinguished. However, the reliability of the instrument decreased slightly; instead of agreeing on all 136 MAEs assessed, the two pharmacists disagreed in 6 cases.

It was concluded that the most useful predictors of an MAE's severity are the legal classification of the drug involved, its therapeutic index, whether the MAE resulted in a drug being used outside the recommendations in its data sheet and the number of times the MAE was repeated consecutively in the same patient. Route of administration was not important. The instrument developed has high reliability and is quick and simple to use. Unfortunately, its validity may be lower than desired, and it was therefore decided to use the subjective method described in Chapter Eight to assess MAE severity in the present study.

Appendix 11

Letter used to recruit health care professionals

FIELD(name) DATE
FIELD(title)
FIELD(address1)
FIELD(address2)
FIELD(address3)
FIELD(address4)

Dear FIELD(letteraddress)

Did you know that about 1 in 30 drug doses is either not given or is given incorrectly? Our research has shown that this is standard for inpatients in UK hospitals and I am writing to ask for your help in improving this situation.

We suspect that some of these failures in the medication distribution system are of little consequence, while others could result in severe patient harm. One difficulty is that we do not currently have a way of identifying which are important. I am developing a scale to measure the potential clinical significance of failures in the system.

I would like your help in validating this scale, by rating a series of cases in terms of their potential clinical significance, on a simple ten point scale. This will take about thirty minutes. As a token of thanks, a £10 gift voucher will be sent to each volunteer who returns the completed form. I am writing to a sample of health care professionals in a range of hospitals and would like you to take part.

If you could participate, please return the slip at the bottom of this letter in the Freepost envelope provided, as soon as possible. Please feel free to contact me on 0171 753 5940 if you have any questions.

I hope to hear from you soon,

Yours sincerely

Bryony Dean (Miss) BPharm MSc MRPharmS
Research/Clinical Pharmacist

-
Yes, I will help in the validation of the rating scale.

FIELD(name), FIELD(address1), FIELD(address2), FIELD(address3), FIELD(address4)

Appendix 12

**The fifty cases scored by the health care professionals
recruited**

Appendix Twelve: The fifty cases scored by the health care professionals recruited

The thirty judges were asked to score the following cases. The right hand column shows their mean scores and for those cases with known outcomes, the severity of the outcome.

- | | |
|--|----------------|
| 1. A hypertensive patient had his blood pressure controlled with enalapril 2.5mg once daily. One dose was missed. | 2.6 |
| 2. An elderly patient with a cardiac pacemaker was prescribed enteric coated aspirin 75mg once daily. One dose was omitted. | 1.7
(Minor) |
| 3. A patient was prescribed lithium carbonate 600mg daily (one tablet), but was given a single dose of 1200mg (two tablets). | 5.3 |
| 4. The first two doses of chloramphenicol eye ointment, prescribed to be administered four times a day, were omitted in a patient with a suspected conjunctivitis. | 2.8 |
| 5. An elderly patient with swallowing difficulties was prescribed ranitidine effervescent tablets 150mg twice daily, for the prophylaxis of ulceration while on diclofenac therapy. An ordinary non-soluble ranitidine tablet was given instead, which the patient swallowed with some difficulty. | 2.6
(Minor) |
| 6. A patient had been receiving warfarin 5mg daily, which was stopped when her INR was found to be 5.4. However for three days she continued to receive a daily dose of warfarin 5mg. | 8.2 |

7. A patient was prescribed vitamin B compound strong tablets, two daily. One dose of only one tablet was given.	1.1 (Minor)
8. A patient with oral Candida was prescribed fluconazole 50mg daily for one week. Fluconazole 200mg capsules were dispensed, which the patient received for the week's course.	4.2
9. A patient prescribed Lacrilube eye drops for her dry eyes was given instead one dose of 30ml lactulose orally.	2.0
10. A patient with an itchy rash was prescribed calamine lotion to be applied three times a day. The first five doses were omitted.	2.1
11. A patient with a history of heart failure was administered a dose of oral atenolol 100mg which was intended for another patient.	7.1 (Severe)
12. A patient was prescribed six doses of oral folinic acid (15mg three times a day) as rescue therapy following methotrexate treatment. The patient instead received six doses of folic acid 15mg.	6.3 (Moderate)
13. An elderly patient prescribed oral co-amilofruse 2.5/20 (Frumil LS) once a day, for the treatment of mild heart failure, was instead given a dose of co-amilofruse 5/40 (Frumil).	4.0
14. A patient was prescribed soluble insulin 10 units every six hours. This was initially interpreted as 10ml (1000 units), but the mistake was realised and the injection stopped after 2ml (200 units) had been given.	9.3 (Severe)
15. A patient prescribed 5mg morphine IV was given intravenously 5mg of Oramorph (oral morphine solution 10mg/5ml) solution.	6.5 (Moderate)

16. A patient was being treated for acute sciatica by lumbar epidural injection of methylprednisolone acetate. The vial of drug was reconstituted with 30% sodium chloride instead of 0.9% sodium chloride and then administered.	7.6 (Severe)
17. A patient with chronic obstructive airways disease was prescribed Augmentin 250/62 suspension, 5ml three times daily for the treatment of a chest infection. The first five doses were omitted.	6.2
18. One 10pm dose of oral metronidazole 400mg was omitted in a patient receiving the drug three times daily for surgical prophylaxis. He was three days post surgery.	2.3
19. A patient with a known penicillin allergy was prescribed oral ciprofloxacin 500mg twice a day for the treatment of a chest infection. He was given one dose of flucloxacillin 500mg.	7.5
20. A patient was prescribed 100mg lamotrigine daily. Lamotrigine 100mg tablets were dispensed instead of the 25mg tablets intended. The patient therefore received 400mg daily for six days instead of 100mg daily.	6.5
21. One dose of oral hydrocortisone 10mg was omitted in a patient with chronic adrenal insufficiency who was prescribed 20mg every morning and 10mg every evening.	5.1
22. An elderly patient prescribed paracetamol suspension 250mg/5ml in a dose of 10ml (500mg) every six hours was given one dose of 20ml (1g).	1.5 (Minor)
23. One dose of oral metformin 500mg was omitted in a diabetic	3.2

patient receiving 500mg three times daily.

24. A patient prescribed 10ml of morphine elixir 2.5mg/5ml (5mg morphine) was given instead a dose of 10ml of the concentrated elixir 100mg/5ml (200mg morphine). 8.8

25. A patient was receiving oral ranitidine 150mg twice a day as prophylaxis against peptic ulceration, while he was also receiving steroids. One evening dose of the ranitidine was missed. He had no history of peptic ulceration. 1.8

26. A patient was prescribed oral vancomycin 125mg four times a day for the treatment of *Clostridium difficile* colitis. Three days into therapy, two consecutive doses were omitted. 3.8

27. A patient with long standing Parkinson's disease was prescribed co-beneldopa 250mg (benserazide 50mg and levodopa 200mg) four times a day, but was dispensed a week's supply of modified release co-careldopa 250mg (carbidopa 50mg and levodopa 200mg) in a bottle labelled co-beneldopa. *

28. A patient with Crohn's disease was prescribed prednisolone enteric coated tablets 5mg once daily, but was given plain uncoated 5mg prednisolone tablets throughout his four day hospital stay. 3.0

29. An elderly patient was prescribed oral ranitidine 150mg twice a day as prophylaxis against NSAID-induced ulceration. The first six doses were omitted. 4.4

30. A patient prescribed oral penicillin 250mg four times daily was dispensed penicillamine 250mg, which the patient was given for three 5.6

days before the error was discovered.

- | | |
|---|-------------------|
| 31. One dose of oral diltiazem 60mg was omitted in a newly admitted patient with angina who normally took the drug three times a day. | 3.5
(Moderate) |
| 32. A newly diagnosed asthmatic patient was prescribed beclomethasone 100 mcg per metered dose, two puffs twice a day. He was given an inhaler containing 250mcg beclomethasone per metered dose, containing sufficient quantity for three weeks. | 3.7 |
| 33. A patient written up for warfarin 10mg was given two 5mg tablets that had expired one month previously. | 2.5 |
| 34. A patient was prescribed thyroxine 25 microgrammes daily. The patient was instead administered methotrexate 25mg daily for several days. | 7.1 |
| 35. An elderly patient prescribed digoxin elixir 125 micrograms daily for the treatment of chronic atrial fibrillation was given 50 micrograms of the elixir daily for several weeks. | 6.2 |
| 36. A terminally ill patient was prescribed morphine sulphate SR tablets 60mg twice daily. He was given a dose of 60mg Sevredol (non-modified release morphine sulphate) rather than the intended MST tablets. | 4.7
(Moderate) |
| 37. A patient prescribed vancomycin 1g IV twice daily was given one of the doses as a bolus rather than by infusion. | 7.1
(Severe) |
| 38. A patient was prescribed gentamicin ear drops, two drops three times a day to the right ear, for the treatment of an ear infection shown | 1.9
(Minor) |

to be sensitive to gentamicin. On the second day of treatment, one dose was administered to the left ear instead of the right ear.

- | | |
|--|-----------------|
| 39. The first two doses of topical Teejel (choline salicylate dental gel BP), prescribed to be applied four times daily, were omitted in a patient with mouth ulcers. | 1.5 |
| 40. A patient prescribed cefotaxime 1g IV three times a day for post-partum pyrexia had a dose reconstituted with 10ml of 15% potassium chloride solution instead of 0.9% sodium chloride. The dose was then administered by bolus injection. | 9.6
(Severe) |
| 41. An elderly non-diabetic patient was given another patient's 5mg glibenclamide tablet. | 6.5
(Severe) |
| 42. An elderly patient with cellulitis was prescribed oral flucloxacillin 1g four times daily. One week after the start of the treatment she was given two consecutive doses of 500mg instead of 1g. | 1.9 |
| 43. An elderly patient with a hospital-acquired chest infection was prescribed cefotaxime 1g IV three times a day. Two days into the treatment course he was given one oral dose of cephadrine 500mg instead of the dose prescribed. He was able to swallow oral medication. | 2.8 |
| 44. One dose of salbutamol 400mcg rotacaps was omitted in a patient with chronic obstructive airways disease. | 3.4 |
| 45. A patient stabilised on warfarin 5mg daily was given one dose of 7.5mg. | 4.7 |

46. A patient who was prescribed oral diltiazem 60mg three times a day was given instead one dose of diazepam 60mg.	8.0
47. A patient prescribed oral diclofenac 50mg three times a day for post-operative pain control missed the first three doses.	4.6
48. A patient with oesophagitis was prescribed omeprazole (Losec) 20mg daily. For three days the patient instead received frusemide (Lasix) 20mg.	5.6 (Moderate)
49. A patient with anaemia was prescribed oral ferrous sulphate 200mg three times a day. One dose was omitted.	0.9
50. A patient prescribed Augmentin (co-amoxiclav 250/125), one tablet three times a day for a chest infection, was given one dose of two tablets on the third day of therapy. Her renal function was normal.	1.4

Footnote:

* This case was not scored by five of the thirty health care professionals; it was therefore excluded from the analysis.

Appendix 13

Instructions for assessing the severity of medication administration errors

FIELD(name)
FIELD(title)
FIELD(address1)
FIELD(address2)
FIELD(address3)
FIELD(address4)

DATE

Dear FIELD(letteraddress)

Thankyou for agreeing to help validate a scale to assess the significance of failures in the drug distribution system. The scale will be used in a project to develop drug distribution systems which are safer for patients and convenient for hospital staff.

Enclosed are brief descriptions of fifty examples of failures in the drug distribution system that resulted in patients not receiving their medication as intended. Please could you rate each of these in terms of their *potential clinical significance*. The scale runs from zero to ten, where zero should be given to an incident which will have no effects on the patient and ten should be given to an incident that would result in death. Mark the scale clearly by either circling the appropriate number or placing a clear mark anywhere between the numbers. Assume that all patients are adults on general medical or surgical wards. Please could you also record how long it takes for you to complete the assessment of all fifty cases. If you have any additional comments please include these in the space provided.

I have asked staff of different disciplines and grades to take part, so that a wide range of health care professionals are represented. Your responses are therefore important, so please rate the cases yourself. All replies will be anonymous and will be pooled with those of other health care professionals to produce an average score for each case.

Please return the completed scoring sheets using the Freepost envelope provided within two weeks. If you have any questions please do not hesitate to contact me on 0171 753 5940.

With many thanks for your help,

Yours sincerely,

Bryony Dean (Miss) BPharm MSc MRPharmS
Research/Clinical Pharmacist

Appendix 14

Criteria used to assess the suitability of patients' own drugs for continued use

Appendix Fourteen: Criteria used to assess the suitability of patients' own drugs for continued use

The following criteria were used at the study hospital to determine if patients' own drugs were suitable for continued use during their stay. This list is reproduced from the pharmacy department's procedures for the management of patients' own drugs.

Medicines may be designated as suitable if:

Container and labelling

- clearly labelled with name of patient
- clearly labelled with name and strength of drug
- clearly labelled with name and address of supplier
- label is legible and clean
- container intact and reasonably clean
- in suitable packaging/container - no envelopes or plastic bags

Medicine

- originally dispensed for the patient concerned
- dispensed within last 6 months unless a blister pack with a clear expiry date shown
- positively identifiable and the same as that written on the label
- in good condition - clean, whole and without visible signs of deterioration
- ointments and creams in pots within six months of dispensing and within expiry date
- sealed, unused mixtures, eye drops, ear drops etc.
- no more than one drug in a single container
- number of doses in container does not exceed number on label
- not a foreign product without a product license

- not a medication with a short shelf-life eg. glyceryl trinitrate, or one which requires storage in a fridge

Storage

- Measures have been taken to ensure that the medicine has been stored appropriately

Appendix 15

**Data collection form used to record opportunities for
error and medication administration errors**

Appendix 16

**Description of each medication administration error
identified**

Appendix Sixteen: Description of each medication administration error identified

Surgical ward, traditional ward pharmacy system ^a

Patient	Date ^b	Time	Events observed ^e	No of MAEs ^c	Type ^{d,e} & severity score	Stage ^f	Additional information, likely causes and contributing factors.
AA	15 Jan	10 pm	A patient with hyperlipidaemia and ischaemic heart disease was prescribed 20mg pravastatin once daily. One dose was omitted.	1	Omission 0.8	A <i>Rx</i>	The medication order had been changed from 20mg at 6 am to 20mg at 10 pm and was therefore not very clear. The nurse apparently did not realise that a dose was due at 10 pm.
AA	16 Jan	10 pm	A patient with hyperlipidaemia and ischaemic heart disease was prescribed 20mg pravastatin once daily. A dose was omitted, the previous day's dose also having been omitted.	1	Omission 1.4	S	The supply previously dispensed for this patient had been exhausted.
BO	12 Jan 14 Jan 15 Jan 16 Jan	6 am 6 am 6 am 6 am	A patient with severe asthma was prescribed prednisolone 30mg once daily. On four mornings out of seven, she was given enteric coated prednisolone instead of the uncoated preparation.	4	Form 0.1	A	One some mornings the patient received the uncoated tablets, on others she received the enteric coated tablets; this depended upon which nurse was administering the morning medication.
BO	17 Jan 18 Jan 19 Jan	10 pm 6 am 6 am	A patient with severe asthma was prescribed nebulised ipratropium bromide 500mcg four times daily. Three doses were omitted during a two day period.	3	Omission 4.6	A <i>Rx (2)</i>	The medication order was written as 'Atrovent', whereas generic ipratropium bromide was stocked on the ward. The nurse did not realise that the two were equivalent and omitted two doses. The third dose was omitted because the previous 6 am dose was unsigned and the nurse apparently did not notice that a dose was due.
BO	18 Jan	6 am	A patient with severe asthma was prescribed nebulised salbutamol 2.5mg four times daily. One morning she received instead a dose of 5ml 0.9% sodium chloride.	1	Drug 3.4	A	Interpretation or selection error.
EN	17 Jan	noon	An elderly diabetic man with infected leg ulcers was being treated with oral ciprofloxacin 250mg twice daily, with doses scheduled for 6 am and 6 pm. On the fifth day of the seven day course he received an additional dose of 250mg at noon.	1	Extra 0.8	A	The nurse apparently thought that a dose was due at this time; the extra dose was signed for.

EN	17 Jan	10 pm	An elderly diabetic man with infected leg ulcers was being treated with oral co-amoxiclav 750mg three times daily. On the second day of therapy he was given a dose of 375mg instead of 750mg.	1	Dose 2.1	A	Interpretation or selection error.
GO	12 Jan	6 am	An elderly man with prostatic enlargement was treated with finasteride 5mg once daily. A dose was omitted; he had not received any of this medication for seven days.	1	Omission 3.1	S	This drug was not in the hospital formulary, and therefore not available.
GO	12 Jan 13 Jan	6 pm 6 am	An elderly man with post-operative gastric stasis was prescribed cisapride 10mg three times daily. The first two doses were omitted.	2	Omission 2.1	S	This newly prescribed drug was not yet available on the ward.
GO	17 Jan	noon	An elderly man was prescribed a seven day course of oral ciprofloxacin 500mg bd for the treatment of a post-operative wound infection. On the second day of therapy, one dose was omitted.	1	Omission 2.4	A	The nurse apparently did not notice that this dose was due.
HAL	12 Jan	6 pm	One dose of oral aspirin 75mg once daily was omitted in a patient with ischaemic heart disease.	1	Omission 0.5	S	The stock supply of 75mg aspirin tablets had been exhausted.
HAL	15 Jan	10 pm	A patient with hyperlipidaemia and ischaemic heart disease was prescribed simvastatin 10mg each night. One dose was missed.	1	Omission 0.8	S	The patient had been transferred from the intensive care unit without her medication, and none was available on the surgical ward.
HAR	12 Jan 13 Jan	6 pm 6 pm	An elderly lady with glaucoma was prescribed timolol 0.5% eye drops twice daily to the right eye. Two doses were omitted on two consecutive days.	2	Omission 2.6	A	The nurses looked unsuccessfully in the drug trolley for these drops, which were stored at the patient's bedside. The medication order was subsequently rewritten onto a new drug chart as once daily. This may have been because the doctor was looking at the administration record and assumed that the medication was only due once a day.
HAR	18 Jan 19 Jan	6 am 6 am	An elderly lady with glaucoma was prescribed timolol 0.5% eye drops once daily to the right eye. Two doses were omitted on two consecutive days.	2	Omission 2.9	A	The nurses apparently did not notice that these doses were due.
HAR	13 Jan	6 am	An elderly lady with angina was prescribed amlodipine 5mg once daily. One dose was omitted.	1	Omission 3.6	A	The nurse could not find this medication in the drug trolley; the box was in amongst other similar boxes.
HAS	12 Jan 13 Jan	10 pm 6 am	An elderly lady was prescribed soluble paracetamol 1g four times daily for post-operative pain relief. Two consecutive doses were omitted.	2	Omission 2.6	S	The stock supply of this drug had been exhausted. Some non-soluble paracetamol tablets were available, which the patient had swallowed without difficulty on previous occasions.

HI	17 Jan	10 pm	One dose of senna was omitted in a patient taking two tablets daily on a regular basis.	1	Omission 1.9	A	The nurse apparently did not see that this dose was due.
KA	12 Jan	6 am	An elderly lady had hypertension which was controlled with atenolol 50mg daily. One dose was omitted.	1	Omission 1.6	A	The nurse could not find this medication in the drug trolley, although it was present.
KA	14 Jan	10 pm	A patient with chronic pruritus was prescribed hydroxyzine 10mg in the morning and 25mg at night. One night-time dose of 25mg was omitted.	1	Omission 1.9	S	The supply dispensed for this patient had been exhausted.
KA	16 Jan	noon	An elderly patient with vertigo was prescribed cinnarizine 15mg three times a day. One dose was omitted.	1	Omission 2.1	S	The supply dispensed for this patient had been exhausted.
LI	14 Jan	6 am	A newly admitted patient was prescribed vitamin capsules BPC, one tablet daily. One dose was omitted.	1	Omission 0	S	No medication had yet been dispensed for this newly admitted patient.
LI	14 Jan	6 am	A newly admitted patient was prescribed ascorbic acid 100mg once daily. One dose was omitted.	1	Omission 0	S	No medication had yet been dispensed for this newly admitted patient.
I.I	15 Jan	6 am	A patient with angina was prescribed diltiazem SR 90mg twice daily. One dose was omitted.	1	Omission 3.4	A	The nurse signed for the administration of this dose, but did not place any diltiazem in the tablet cup.
MA	12 Jan	6 am	An elderly man was prescribed olive oil ear drops three times daily, to soften impacted ear wax. The first dose was omitted.	1	Omission 0.8	S	This drug was newly prescribed and a supply had not yet been dispensed.
OS	14 Jan	6 am	A patient's cardiac arrhythmias had been treated with intravenous amiodarone. This was then changed to oral amiodarone 200mg twice daily. The first oral dose was omitted.	1	Omission 1.6	S	The oral drug was newly prescribed and had not yet been dispensed.
OS	14 Jan 14 Jan	6 am 10 pm	A patient with hyperkalaemia was prescribed oral calcium resonium, 15g three times daily. One the third day of treatment, the 6 am and 10 pm doses were both omitted. Her serum potassium level was 5.2 mmol/L at that time.	2	Omission 2.6	A	The nurse intended to return to administer this drug, as it required dispersing in water. However it was not subsequently administered.
OS	15 Jan	10 pm	An elderly patient with cardiac arrhythmias was prescribed oral amiodarone (200mg twice daily for 7 days and then 200mg daily), following intravenous therapy. On the second day of the twice daily regime she missed one dose, having also missed a dose the previous day.	1	Omission 2.9	A Rx	The medication order was confusing, and the nurse was not sure whether or not the dose should be given. She therefore omitted it.
TO	16 Jan	10 pm	A patient with hyperlipidaemia and ischaemic heart disease was prescribed pravastatin 20mg daily. One dose was omitted.	1	Omission 0.8	S	The dispensed supply of this medication had been exhausted.
TO	17 Jan	10 pm	A patient with angina was prescribed isosorbide mononitrate 20mg three times daily. A dose of amlodipine 20mg was instead given.	1	Drug * 4.6	A Rx	The drug was prescribed as 'ISMN'. The nurse interpreted this as 'ISTIN' and prepared 20mg of amlodipine.

TO	18 Jan	6 am	A patient with gastro-oesophageal reflux was prescribed cisapride 10mg three times daily. The first dose was omitted.	1	Omission 1.3	A	This medication was newly prescribed and the nurse assumed that none was available. However, there was already a supply in the drug trolley.
WA	17 Jan	6 am	A patient was prescribed clarithromycin 250mg twice daily for the eradication of <i>Helicobacter pylori</i> . The first dose was omitted.	1	Omission 1.1	S	This newly prescribed drug was not yet available on the ward.
WA	17 Jan	6 pm	A patient with hypokalaemia was prescribed potassium chloride 1mmol/ml oral liquid, 10ml three times a day. On the second day of treatment, one dose was omitted.	1	Omission 1.4	A	The nurse could not find this drug in the trolley, although it was present.
WA	17 Jan 18 Jan	6 pm 6 am	A patient was prescribed clarithromycin 250mg twice daily for the eradication of <i>Helicobacter pylori</i> . The second and third doses were omitted, the first dose had also been omitted.	2	Omission 2.3	A	The nurse could not find this drug in the trolley, although it was present.
WA	19 Jan	6 am	A patient was prescribed oral metronidazole suspension, 400mg three times daily, as part of an eradication regime for <i>Helicobacter pylori</i> . One dose of 200mg was given.	1	Dose 1.1	A	The 200mg/5ml suspension was measured in an ungraduated paper tablet cup, and about one quarter of a cupful (approximately 5ml) administered.
WH	12 Jan 12 Jan 13 Jan 13 Jan 14 Jan 16 Jan	noon 10 pm 6 am 10 pm noon 6 am	A patient was prescribed betahistine 16mg three times a day to treat the symptoms of vertigo. On six occasions during a one week period she was given 8mg instead of 16mg.	6	Dose 2.4	A <i>Rx</i>	The medication order was written as 'one tablet' of 'Serc-16'. A supply of 8mg tablets had been dispensed, of which two were required for each dose. However this had not been endorsed on the drug chart and on many occasions only one tablet was administered.
WH	12 Jan 13 Jan	10 pm 6 am	A patient was prescribed long-term oxybutinin 5mg three times daily for bladder instability. Two consecutive doses were omitted.	2	Omission 1.6	S	The dispensed supply of this medication had been exhausted.
WH	14 Jan 17 Jan	noon noon	A patient was prescribed long-term oxybutinin 5mg three times daily for bladder instability. Two doses were omitted during a three day period, two other doses had also been omitted in the previous two days.	2	Omission 2.1	A	The nurse could not find this drug in the trolley, although it was present.
WH	17 Jan	6 pm	A patient was prescribed clonidine 50 micrograms twice daily for the prophylaxis of migraine. One dose was omitted.	1	Omission 1.4	S	The dispensed supply of this medication had been exhausted.
WH	18 Jan	6 am	A patient was prescribed long-term oxybutinin 5mg three times daily for bladder instability. One dose was omitted.	1	Omission 1.6	S	The dispensed supply of this medication had been exhausted.

WH	15 Jan 15 Jan 16 Jan	6 am 6 pm 6 am	A patient was prescribed ciprofloxacin 500mg twice daily for five days for the treatment of an infected leg ulcer. Three additional doses were given after the five day course had been completed.	3	Extra 1.1	A Rx	The prescription was given a valid period of five days, but the administration section of the drug chart was not crossed through and the drug therefore continued.
WH	15 Jan	noon	Dicyclomine 20mg three times daily was prescribed for the control of a patient's bladder spasm. One dose of 10mg was given instead of 20mg.	1	Dose 1.6	A	Interpretation or selection error.
WH	16 Jan	noon	A patient was prescribed betahistine 16mg three times a day to treat the symptoms of vertigo. One dose was omitted.	1	Omission 1.3	S	The dispensed supply of this medication had been exhausted.
WH	16 Jan	6 pm	One SandoCal 400 tablet (effervescent calcium carbonate/lactate) was prescribed to be given twice a day for the prevention of osteoporosis in a patient taking long term corticosteroids. Two tablets were given instead of one.	1	Dose 0.3 **	A	Interpretation or selection error.
WH	18 Jan	6 am	Dicyclomine 20mg three times daily was prescribed for the control of a patient's bladder spasm. Three consecutive doses were omitted.	3	Omission 2.4	S	The dispensed supply of this medication had been exhausted.

Footnotes

- a: Gavison and lactulose wrong dose errors are excluded.
- b: Dates refer to 1998; 12th January was a Monday.
- c: MAEs = medication administration errors; figures refer to the number of MAEs that occurred
- d: 'Drug' = wrong drug; 'Dose' = wrong dose; 'Extra' = extra dose; 'Form' = wrong form; 'Unordered' = unordered drug.
- e: * = observer intervened to prevent the error; ** = patient prevented the error.
- f: Stage of the drug distribution system in which the MAEs originated. 'A' = administration; 'S' = supply; 'Rx' = ambiguous or unclear prescription that apparently contributed to the error.
- g. Information used to score the severity of the event.

Surgical ward, patients' own drugs system ^a

Patient	Date ^b	Time	Events observed ^a	No of MAEs ^c	Type ^{d,e} & severity score	Stage ^f	Additional information, likely causes and contributing factors.
AH	8 Apr	6 am	A patient with angina was prescribed nifedipine SR 20mg twice daily. She was given one dose of nifedipine SR 10mg.	1	Dose 2.4	A	The supply in this patient's box consisted of 10mg tablets, of which two should have been given. Only one 10mg tablet was administered.
BAI	3 Apr	6 am	A patient with symptoms of gastro-oesophageal reflux was prescribed cisapride 20mg twice a day. The first dose was omitted.	1	Omission 0.5	S	This newly prescribed drug was not yet available on the ward.
BAI	4 Apr	6 am	A patient with symptoms of gastro-oesophageal reflux was prescribed cisapride 20mg twice a day. On the second day of therapy she was given a dose of only 10mg.	1	Dose 1.4	A	One 10mg tablet was administered instead of two.
BAR	3 Apr 8 Apr	10 pm 10 pm	A post-operative patient was prescribed dihydrocodeine 60mg four times daily, as well as paracetamol. Two doses of only 30mg dihydrocodeine were given.	2	Dose 1.3	A	Many patients on the ward were prescribed regular dihydrocodeine; some were prescribed 30mg, others 60mg.
BAR	4 Apr 5 Apr	noon 6 am	A patient with depression was receiving sertraline 50mg twice daily. Two consecutive doses were omitted.	2	Omission 1.9	S	The supply dispensed for this patient had been exhausted.
BAR	4 Apr	10 pm	A post-operative patient was prescribed paracetamol 1g four times daily, as well as dihydrocodeine. One dose of paracetamol was omitted.	1	Omission 0.8	A	The previous evening, a nurse had signed for the administration of the paracetamol so that her signature overlapped into the next day's administration box. The next evening, the nurse assumed that the 10pm dose had already been given.
BAR	5 Apr 6 Apr 6 Apr	6 pm 6 am 6 pm	A patient was prescribed betahistine 16mg twice daily for treatment of the symptoms of vertigo. Three consecutive doses were omitted.	3	Omission 2.6	S	The supply dispensed for this patient had been exhausted.
BAR	7 Apr	noon	A patient with depression was receiving sertraline 50mg twice daily. One dose was omitted.	1	Omission ** 0.9	A	The nurse apparently did not see that this dose was due.
BAR	8 Apr	noon	A patient with depression was receiving sertraline 50mg twice daily. One dose was omitted; a dose had also been omitted on the previous day.	1	Omission 1.9	A	The nurse intended to return and administer this medication, but did not do so.

BAR	8 Apr	noon	A patient was receiving oral metronidazole 400mg three times a day, for the treatment of <i>Clostridium difficile</i> colitis. On the fifth day of the course, one dose was omitted.	1	Omission 2.4	A	The nurse intended to return and administer this medication, but did not do so.
BAR	8 Apr	noon	A post-operative patient was prescribed paracetamol 1g four times daily, as well as dihydrocodeine. One dose of paracetamol was omitted.	1	Omission 0.8	A	The nurse intended to return and administer this medication, but did not do so.
BAR	8 Apr	noon	A post-operative patient was prescribed dihydrocodeine 60mg four times daily, as well as paracetamol. One dose was omitted.	1	Omission 1.6	A	The nurse intended to return and administer this medication, but did not do so.
BAR	8 Apr	10 pm	A patient was prescribed betahistine 16mg twice daily at 6 am and 6 pm for treatment of the symptoms of vertigo. An additional dose of 16mg was given at 10 pm.	1	Extra 1.1	A	The nurse apparently thought that a dose was due at this time. The additional dose was signed for on the drug chart
BE	3 Apr	noon	A patient with depression was receiving sertraline 50mg once daily. One dose was omitted.	1	Omission 1.1	S	The supply dispensed for this patient had been exhausted.
BE	5 Apr	6 am	A patient with was prescribed azathioprine 50mg once daily for the treatment of his rheumatoid arthritis. A dose was omitted.	1	Omission 2.1	S	The supply dispensed for this patient had been exhausted.
BE	6 Apr 7 Apr	6 am 6 am	A patient with rheumatoid arthritis was prescribed soluble prednisolone 20mg once daily. Two consecutive doses were prepared using crushed enteric-coated tablets.	2	Form 1.6	A Rx	Although soluble tablets were available, the nurse crushed the enteric coated insoluble tablets. The medication order was difficult to interpret, having been changed from enteric coated tablets to soluble tablets.
BE	6 Apr	6 am	A patient receiving oral prednisolone was prescribed omeprazole 20mg once daily as prophylaxis against peptic ulceration. One dose was prepared by crushing the enteric coated pellets.	1	Deteriorated * 1.6	A	This patient was being fed via a nasogastric tube and the nurse crushed all of his medication, including the omeprazole pellets, prior to administration.
BO	2 Apr	10 pm	A patient with chronic obstructive airways disease was prescribed slow-release acetazolamide 250mg once daily. The first dose was omitted.	1	Omission 0.6	S	This newly prescribed medication was not yet available on the ward.
BO	3 Apr	6 am	A diabetic patient was receiving gliclazide 160mg once daily. One dose was omitted.	1	Omission 2.4	S	The supply brought in by this patient had been exhausted and a further supply not yet dispensed.
BO	6 Apr	10 pm	A patient with chronic obstructive airways disease and a chest infection was prescribed ciprofloxacin 750mg twice daily. On the fourth day of therapy, a dose of only 250mg was given.	1	Dose 1.4 *	A	Interpretation or selection error.
BO	7 Apr	noon	A patient with chronic obstructive airways disease and a chest infection was prescribed ipratropium bromide 500 mcg four times daily. One dose was omitted.	1	Omission 2.1	S	The stock supply of this medication had been exhausted.

BO	7 Apr	10 pm	A patient with chronic obstructive airways disease and a chest infection was prescribed nebulised salbutamol 2.5mg four times daily. One dose of 5mg was administered.	1	Dose 1.3	A	Interpretation or selection error; two of the 2.5mg nebuluses were selected instead of one.
CA	2 Apr	6 am	A patient had been receiving two vitamin B compound strong tablets, once daily. One dose was omitted.	1	Omission 0.3	A	A supply had been dispensed for this patient, but it had been placed in the drug trolley instead of in his box. The nurse unsuccessfully looked for it in his box.
CA	3 Apr	6 am	A patient suffering from depression was prescribed fluoxetine 20mg daily. One dose was omitted.	1	Omission 1.8	S	The supply dispensed for this patient had been exhausted.
CH	6 Apr	6 am	A patient was receiving ascorbic acid 200mg once daily. One dose of 100mg was administered.	1	Dose ** 0.3	A	Only one 100mg tablet was selected, instead of two.
GR	6 Apr 7 Apr 7 Apr	10 pm 6 am 10 pm	A patient was prescribed metronidazole 400mg three times daily for the treatment of a post-operative infection. Three doses were omitted after four days of treatment.	3	Omission * 3.1	A	The nurses apparently did not see that these doses were due. The observer intervened to prevent the omission of the second dose.
GR	8 Apr	noon	A patient had been prescribed metronidazole 400mg three times daily for five days, for the treatment of a post-operative infection. An additional dose was given after the course had been completed.	1	Extra 0.3	A <i>Rx</i>	The medication order had been crossed off on the administration side of the drug chart, but not through the order itself. The nurse administered the medication and only realised that the drug had been stopped when he came to sign for its administration.
HA	2 Apr 3 Apr 3 Apr 3 Apr	10 pm 6 am noon 10 pm	A patient was prescribed four prophylactic doses of sodium fusidate 500mg three times daily after orthopaedic surgery. She did not receive any of this medication.	4	Omission 4.1	S	The drug was not available on the ward. The nurses did not request any of this drug from the pharmacist and none was supplied.
HUB	2 Apr	6 pm	A patient with hypertension was prescribed doxazosin 1mg twice daily. One dose was omitted.	1	Omission 2.1	A	The drug chart was not available during the 6 pm round, and the dose not administered subsequently.
HUM	2 Apr	10 pm	A patient with congestive heart failure was prescribed enalapril 10mg twice daily. One dose was omitted.	1	Omission ** 1.6	A <i>Rx</i>	The evening dose had been changed from 6 pm to 10 pm. The altered drug chart was untidy and the nurse did not notice that the dose was due.
IP	5 Apr	noon	A patient was prescribed codeine 60mg twice daily for pain relief following surgery. A dose was omitted.	1	Omission ** 1.6	S	The stock supply of codeine tablets had been exhausted when the 6 am dose was due. By noon, a new bottle had been supplied and the 6 am dose given late following the patient's intervention.

KI	7 Apr 8 Apr	6 am 6 am	A patient with hypertension was prescribed losartan 75mg once daily. On two consecutive days, only 50mg was given.	2	Dose ** 2.1	A	The patient had a supply of the 50mg tablets in his box, of which 1.5 tablets should have been given. However, only one tablet was administered. On the second morning, the patient intervened.
MC	4 Apr	10 pm	A nil-by-mouth patient with a clotting disorder was prescribed vitamin K injection, 10mg once daily. Instead she received orally one Sando K tablet (potassium chloride 12 mmol).	1	Drug * 4.4	A	The nurse apparently interpreted the medication order as Sando K.
PO	4 Apr	6 am	A patient with hypokalaemia (serum potassium = 3.1 mmol/L) was prescribed Sando K (potassium chloride 12 mmol), two tablets three times a day. On the second day of therapy only one tablet was given.	1	Dose 2.3	A	Interpretation or selection error.
PO	7 Apr	noon	A patient with chronic obstructive airways disease and a chest infection was prescribed ipratropium bromide 500 mcg four times daily. One dose was omitted.	1	Omission 2.1	S	The stock supply of this medication had been exhausted.
PO	7 Apr	noon	A post-operative patient was prescribed paracetamol 1g four times daily. One dose of paracetamol was omitted.	1	Omission 1.3	S	The stock supply of this medication had been exhausted.
PR	3 Apr	6 pm	A patient with hypertension was prescribed enalapril 20mg twice daily. The first dose was omitted.	1	Omission 1.9	A	The nurse apparently did not see this order on the drug chart.
PR	4 Apr	noon	A post-operative patient was prescribed dihydrocodeine 30mg four times daily. One dose of 60mg was administered.	1	Dose 1.3	A	Two tablets were selected instead of one. Some patients on the ward were prescribed 30mg, others 60mg.
PR	8 Apr	6 am	A patient with hypertension and ischaemic heart disease was prescribed aspirin 150mg once daily. One dose of 75mg was given.	1	Dose 0.0	A	Interpretation or selection error.
SC	7 Apr	6 am	A patient with ischaemic heart disease was prescribed aspirin 75mg once daily. One dose of 150mg was given.	1	Dose 0.3	A	Interpretation or selection error.
SH	7 Apr 8 Apr 8 Apr	10 pm 6 am 10 pm	A newly admitted patient was taking azapropazone 300mg twice daily for her rheumatoid arthritis. The first three doses following her admission were omitted.	3	Omission 2.9	S	The patient had not brought in her own supply of this medication, which was not yet available on the ward.

SO	2 Apr 2 Apr 3 Apr 3 Apr 4 Apr 4 Apr 5 Apr	6 am 6 pm 6 am 6 pm 6 am 6 pm 6 am	An elderly patient with peripheral vascular disease and multiple leg ulcers was prescribed oral slow-release tramadol 200mg twice daily, as well as etodolac and paracetamol. Seven consecutive doses of the tramadol were omitted.	7	Omission 3.6	S	This drug was not in the hospital formulary, and therefore not available.
SO	2 Apr	6 am	A patient with angina was prescribed slow release isosorbide mononitrate, 60mg once daily. A dose of three 20mg non-modified release tablets was given.	1	Form 3.9	A	Interpretation or selection error.
SO	3 Apr	6 am	A patient with angina was prescribed slow release isosorbide mononitrate, 60mg once daily. Once dose was omitted.	1	Omission 3.9	S	The patient's supply of this medication had been depleted.
SO	3 Apr	10 pm	A post-operative patient on regular paracetamol 1g four times daily was also given an unprescribed dose of dihydrocodeine 30mg.	1	Unordered 1.3	A	Many patients on the ward were prescribed dihydrocodeine as well as paracetamol.

Footnotes

- Gaviscon and lactulose wrong dose errors are excluded.
- Dates refer to 1998; 2nd April was a Thursday.
- MAEs = medication administration errors; figures refer to the number of MAEs that occurred
- 'Drug' = wrong drug; 'Dose' = wrong dose; 'Extra' = extra dose; 'Form' = wrong form; 'Unordered' = unordered drug.
- * = observer intervened to prevent the error; ** = patient prevented the error.
- Stage of the drug distribution system in which the MAEs originated. 'A' = administration; 'S' = supply; 'Rx' = ambiguous or unclear prescription that apparently contributed to the error.
- Information used to score the severity of the event.

Medical ward, traditional ward pharmacy system, first data collection period ^a

Patient	Date ^b	Time	Events observed ^e	No of MAEs ^c	Type ^{d,e} & severity score	Stage ^f	Additional information, likely causes and contributing factors.
BU	03 Feb	noon	A patient with chronic renal failure and hypertension had been taking lisinopril 2.5mg once daily. This was changed to 5mg once daily because his blood pressure remained at 140/90. On the day of this change he was given a total dose of 7.5mg.	1	Extra 2.9	A Rx	The patient had already received a dose of 2.5mg at 6 am when the medication order was rewritten. At noon the nurse saw the new medication order and administered an extra dose of 5mg.
DEM	29 Jan	6 am	An immunosuppressed renal transplant patient was prescribed oral nystatin suspension 1ml four times a day for the treatment of an oral <i>Candida</i> infection. The first dose was omitted.	1	Omission 0.8	S	This newly prescribed medication had not yet been supplied.
DEM	29 Jan	10 pm	An immunosuppressed renal transplant patient was prescribed prophylactic co-trimoxazole 480mg twice daily. On the second day after his transplant one dose was omitted.	1	Omission 2.4	A	The nurse apparently did not notice that this dose was due.
DES	31 Jan	6 am	A patient with chronic renal failure was prescribed two CalciChew tablets (calcium carbonate 1.25g) three times daily as a phosphate-binding agent. One dose of one tablet was given.	1	Dose 1.6	A	Interpretation or selection error.
DU	04 Feb	6 am	A patient with chronic renal failure was prescribed alfalcidol 0.5mcg daily. One dose of 0.25mcg was given.	1	Dose 1.0	A	Interpretation or selection error.
GR	27 Jan	noon	A patient with chronic renal failure and CAPD-related peritonitis was prescribed co-amoxiclav 625mg three times daily. On the third day of the course he was given a dose of 375mg.	1	Dose 2.4	A	Interpretation or selection error.
HU	26 Jan	6 am	A patient with chronic renal failure and CAPD-related peritonitis was prescribed co-amoxiclav 325mg three times daily. On the second day of the course he was given a dose of 625mg.	1	Dose 0.8	A Rx	Interpretation or selection error. The dose was prescribed as '250', referring to the dose of amoxycillin in the preparation. The prescription was later changed to 625mg three times daily.
HU	27 Jan	noon	A patient with chronic renal failure and CAPD-related peritonitis was prescribed co-amoxiclav 625mg three times daily. On the third day of the course he was given a dose of 375mg.	1	Dose 2.4	A	Interpretation or selection error.

JO	30 Jan	10 pm	A patient with chronic renal failure suffering from nausea and vomiting was prescribed domperidone 10mg three times a day. One dose was omitted.	1	Omission * 2.4	A	The nurse could not find this product in the drug trolley, although it was present.
NI	31 Jan 31 Jan	noon 10 pm	A patient with chronic renal failure and CAPD-related peritonitis was prescribed co-amoxiclav 375mg three times daily. On the first day of the course she was given two consecutive doses of 625mg.	2	Dose 1.3	A Rx	Interpretation or selection error. The dose was prescribed as '1 tablet'. The prescription was later clarified as being for 325mg three times daily.
PA	03 Feb	noon	A patient with chronic renal failure suffering from nausea and vomiting was prescribed domperidone 10mg three times a day. The first dose was omitted.	1	Omission 2.6	A	This medication order was newly written, and the nurse assumed that none was available. However there was a supply of the drug in the trolley.
PE	03 Feb	10 pm	A patient with chronic renal failure was prescribed one CalciChew tablet (calcium carbonate 1.25g) three times a day as a phosphate-binding agent. One dose of two tablets was given.	1	Dose 1.3	A	Interpretation or selection error.
P'R	02 Feb 02 Feb 03 Feb 03 Feb	6 pm 10 pm 6 am noon	An immunosuppressed renal transplant patient was prescribed amphotericin lozenges, one four times a day, for the treatment of an oral <i>Candida</i> infection. The first four doses were omitted.	4	Omission 2.9	S	The first four doses were omitted because the medication was not yet available in the ward.
PR	03 Feb	6 pm	An immunosuppressed renal transplant patient was prescribed amphotericin lozenges, one four times a day, for the treatment of an oral <i>Candida</i> infection. The fifth scheduled dose was omitted. The patient had already missed the first four doses.	1	Omission 3.1	A	The nurse mistakenly assumed that this product was unavailable and did not look for it in the drug trolley.
SH	28 Jan 29 Jan	6 am 6 am	An elderly lady with chronic renal failure and hypertension was prescribed nifedipine LA 90mg, once daily. On two consecutive days she was instead given nine nifedipine SR 10mg tablets.	2	Form 4.1	A	Interpretation or selection error.
SH	04 Feb	6 am	An elderly lady with chronic renal failure and hypertension was prescribed nifedipine LA 90mg, once daily. She was given a dose consisting of one nifedipine LA 60mg tablet plus three nifedipine SR 10mg tablets.	1	Form * 2.1	A	Interpretation or selection error.
SUF	29 Jan	noon	A patient with chronic renal failure was prescribed oral metronidazole 400mg three times daily for the treatment of CAPD-related peritonitis. On the second day of the course she was given one dose of 200mg.	1	Dose 1.4	A	Interpretation or selection error.

SUN	28 Jan	6 am	An immunocompromised patient with a mycoplasma infection was prescribed doxycycline 100mg once daily. The first dose was omitted.	1	Omission 3.9	S	This newly prescribed medication had not yet been supplied.
SUN	28 Jan	6 am	An immunocompromised patient with tuberculosis was prescribed pyridoxine 10mg once daily to accompany her isoniazid therapy. The first dose was omitted.	1	Omission 0.4	S	This newly prescribed medication had not yet been supplied.
SUN	28 Jan	10 pm	A patient with a previous renal transplant was prescribed Neoral (cyclosporin) 100mg twice daily. One dose was omitted.	1	Omission 3.1	A	The nurse apparently did not notice that this dose was due.
SUN	29 Jan	6 am	A patient with a previous renal transplant was prescribed alfalcaldol 1mcg once daily. One dose of 0.25mcg was given.	1	Dose 1.1	A	Interpretation or selection error.
TU	04 Feb	10 pm	A patient admitted with rejection of a renal transplant was prescribed prednisolone 48mg once daily. One dose of 0.5mg was given.	1	Dose * 5.6	A	Interpretation or selection error.
VA	27 Jan 29 Jan	6 am 6 am	A patient with a previous renal transplant was prescribed prednisolone 10mg three times per week (Mondays, Wednesdays and Fridays). Two extra doses were given, one on a Tuesday and one on a Thursday.	2	Extra 2.4	A Rx	The prescriber had written 'three times a week, M, W, F' on the drug chart but the nurse apparently did not see this instruction.
VA	27 Jan 27 Jan 28 Jan 28 Jan	6 pm 10 pm 6 am noon	An immunosuppressed patient with an oral <i>Candida</i> infection was prescribed nystatin oral suspension, 1ml four times daily. The first four doses were omitted.	4	Omission 3.1	S	This newly prescribed medication had not yet been supplied.
VA	28 Jan 28 Jan 29 Jan 29 Jan 30 Jan 30 Jan 30 Jan	6 pm 10 pm 6 am 6 pm 6 am noon 6 pm	An immunosuppressed patient with an oral <i>Candida</i> infection was prescribed nystatin oral suspension, 1ml four times daily. Having already missed the first four doses, the patient missed the next seven scheduled doses.	7	Omission 4.1	A	The nurses assumed that the patient was self-administering the medication and signed the drug chart accordingly. However the patient had not yet been given the medication, which was in the medicines cupboard.
VA	29 Jan	6 am	An immunosuppressed patient with urinary tract infection was prescribed trimethoprim 200mg twice daily. On the second day of the course a dose was omitted.	1	Omission 2.4	A	The nurse could not find this medication in the drug trolley, although it was present.

VA	29 Jan	6 pm	A patient with constipation was prescribed regular lactulose 20ml twice daily. A dose was omitted.	1	Omission 1.6	A	The nurse apparently did not see that this dose was due.
WH	26 Jan	noon	A patient with a previous renal transplant had been taking prednisolone 20mg daily. This was then reduced to 10mg daily. On the day of this reduction he received 30mg.	1	Extra 2.1	A <i>Rx</i>	The patient had been given a dose of 20mg at 6 am. The doctor rewrote the medication order between 6 am and noon, when a nurse saw the new medication order and administered an additional dose of 10mg.

Footnotes:

- a: Gavison and lactulose wrong dose errors are excluded.
- b: Dates refer to 1998; 16th January was a Monday.
- c: MAEs = medication administration errors; figures refer to the number of MAEs that occurred
- d: 'Drug' = wrong drug; 'Dose' = wrong dose; 'Extra' = extra dose; 'Form' = wrong form; 'Unordered' = unordered drug.
- e: * = observer intervened to prevent the error; ** = patient prevented the error.
- f: Stage of the drug distribution system in which the MAEs originated. 'A' = administration; 'S' = supply; 'Rx' = ambiguous or unclear prescription that apparently contributed to the error.
- g. Information used to score the severity of the event.

Medical ward, traditional ward pharmacy system, second data collection period ^a

Patient	Date ^b	Time	Events observed ^e	No of MAEs ^c	Type ^{d,e} & severity	Stage ^f	Additional information, likely causes and contributing factors.
AB	19 Mar	6 am	A patient with epilepsy was taking phenytoin sodium 350mg once daily. One dose of three 100mg capsules (phenytoin sodium) plus a 50mg chewable tablet (phenytoin base; equivalent to 54mg phenytoin sodium) was given.	1	Dose 0.8	A	Selection error. Some 50mg phenytoin sodium capsules were also available in the drug trolley.
ALB	17 Mar	6 pm	An elderly asthmatic patient was prescribed nebulised salbutamol 2.5mg four times daily. One dose of 10mg was given.	1	Dose 3.4	A	2ml of the 5mg/ml nebuliser solution was measured instead of 0.5ml.
ALE	21 Mar	6 am	A patient with conjunctivitis was prescribed chloramphenicol eye drops, 1 drop into the affected eye four times a day. The first dose was omitted.	1	Omission 1.6	S	This newly prescribed medication was not yet available on the ward.
CA	21 Mar	6 am	A patient with diabetes and ischemic heart disease was prescribed aspirin 75mg once daily. One dose was omitted.	1	Omission 0.6	A	The nurse signed for the administration of this dose, but did not place any aspirin in the medication cup.
CA	22 Mar	6 pm	A diabetic patient was prescribed gliclazide 80mg once daily. One dose was omitted.	1	Omission 2.9	A	The nurse apparently did not notice that this dose was due.
CH	16 Mar	6 am	A patient with chronic renal failure was prescribed two Calcichew tablets (calcium carbonate 1.25g) three times daily, as a phosphate-binding agent. One dose of one tablet was given.	1	Dose ** 1.6	A	Interpretation or selection error.
CO	16 Mar	6 am	A patient recovering from a chest infection and being fed nasogastrically was prescribed nebulised sodium chloride 0.9%, 5ml four times daily. One dose of 5mg salbutamol was given instead.	1	Drug * 2.3	A	Interpretation or selection error.
CO	23 Mar	6 pm	A patient with a history of epilepsy was prescribed phenytoin suspension, 45ml (270mg) once daily. A dose of 50ml (300mg) was given.	1	Dose * 1.3	A Rx	The patient had been previously taking phenytoin sodium 300mg once daily. This had been changed to phenytoin suspension 30mg/5ml for administration via a nasogastric tube. The pharmacist had indicated that 300mg phenytoin sodium was equivalent to 45ml of the suspension (phenytoin base), but 50ml was prepared.

CO	25 Mar	6 am	A patient being fed nasogastrically was prescribed ranitidine syrup 150mg twice daily as prophylaxis against stress ulceration. A dose of 300mg was given.	1	Dose 0.8	A	The syrup was measured in an ungraduated paper medication cup. A whole cupful (about 20ml) was administered.
CO	25 Mar 25 Mar	noon 6 pm	A patient being fed nasogastrically was not absorbing his feed and was prescribed cisapride 10mg three times daily. The first two doses were omitted.	2	Omission 2.6	S	This newly prescribed medication was not yet available on the ward.
CO	25 Mar	6 pm	A patient with a history of epilepsy was prescribed phenytoin suspension, 45ml (270mg) once daily. The bottle was not shaken, resulting in a visible differential concentration.	1	Dose 3.4	A	The correct volume of the suspension was measured but the bottle was not shaken, resulting in a lower dose being administered.
CU	19 Mar	10 pm	A patient with chronic constipation was taking three senna tablets daily. A dose was omitted.	1	Omission 1.4	A	The nurse apparently did not notice that this dose was due.
CU	19 Mar	10 pm	A patient with chronic renal failure and hypertension was prescribed lacidipine 4mg once daily. A dose was omitted.	1	Omission 2.6	S	This medication was not yet available on the ward, although the patient had brought in her own supply..
CU	20 Mar 20 Mar	6 am 6 pm	A patient with chronic constipation was taking docusate sodium 200mg twice daily. Two consecutive doses were omitted.	2	Omission 1.9	S	This medication was not yet available on the ward, although the patient had brought in her own supply..
CU	20 Mar 20 Mar	noon 6 pm	A patient with chronic renal failure was prescribed nystatin oral suspension 1ml four times daily for the treatment of an oral <i>Candida</i> infection. The first two doses were omitted.	2	Omission 2.1	S	This newly prescribed medication was not yet available on the ward.
DE	16 Mar	10 pm	A patient with hypercalcaemia was prescribed Phosphate Sandoz tablets (oral phosphate 16.1mmol), at a dose of two tablets three times daily. The last dose of the five-day course was omitted.	1	Omission 0.5	A <i>Rx</i>	The medication order had been crossed through on the administration side of the drug chart, indicating when the course was to finish. The nurse apparently assumed that the medication order had been discontinued and did not administer the dose.
DI	20 Mar	10 pm	A patient admitted for a renal transplant was prescribed a preoperative dose of ranitidine 150mg. He was instead given a dose of 200mg amiodarone.	1	Drug * 4.9	A	The nurse was preparing another patient's medication, and had placed a dose of amiodarone in a medication cup. The anaesthetist then asked if Mr DI could be given his 10 pm dose of ranitidine immediately. The nurse prepared this dose using a new medication cup, but then selected the cup containing the amiodarone for administration to Mr DI.
DI	21 Mar	6 am	A renal transplant patient was prescribed nystatin oral suspension 1ml four times daily as prophylaxis against oral <i>Candida</i> infection. The first post-operative dose was omitted.	1	Omission 1.8	A	The nurse could not find this medication, although some was present on the ward.
FR	18 Mar	6 am	A patient with chronic renal failure was prescribed alfalcidol 0.5mcg daily. One dose of 0.25mcg was given.	1	Dose 1.0	A	Interpretation or selection error.

GI	20 Mar	10 pm	A patient admitted for a renal transplant was prescribed tacrolimus 1mg twice daily. His pre-operative dose was administered twice.	1	Extra ** 2.9	A	The nurse looking after this patient administered a dose of 1mg but did not sign for its administration. The nurse conducting the drug round assumed that the dose had not been given and administered it again.
GI	22 Mar	6 am	A renal transplant patient was prescribed nystatin oral suspension 1ml four times daily as prophylaxis against oral <i>Candida</i> infection. One dose was omitted two days post-operatively.	1	Omission 0.9	S	The previously dispensed bottle had been broken and a new supply was not yet available.
GI	24 Mar	noon	A renal transplant patient was prescribed Tiralac (calcium carbonate 420mg and glycine 180mg), two tablets three times daily, as a phosphate binding agent. A dose of two Calcichew tablets (calcium carbonate 1.25g) was instead given.	1	Drug 1.3	A	Interpretation or selection error.
GI	25 Mar	6 am	A renal transplant patient was prescribed Tiralac (calcium carbonate 420mg and glycine 180mg), two tablets three times daily, as a phosphate binding agent. One dose was omitted.	1	Omission 1.6	S	This medication was not yet available on the ward, although the patient had brought in his own supply..
LE	17 Mar	noon	A patient with chronic renal failure and hypertension was prescribed lacidipine 6mg once daily. One dose was omitted.	1	Omission ** 3.1	A	The nurse apparently did not notice that this dose was due.
MA	20 Mar	6 am	A patient with cardiac arrhythmias was prescribed a loading dose of amiodarone 200mg three times daily. On the third day of this regime a dose was omitted.	1	Omission 1.9	S	The supply previously dispensed had been exhausted.
MC	16 Mar 17 Mar	6 pm noon	A patient with chronic renal failure and severe pain of unknown origin was prescribed ibuprofen 400mg three times daily. The first two doses were omitted.	2	Omission 2.1	S	This newly prescribed medication was not yet available on the ward.
MC	20 Mar	6 am	A hypertensive patient with chronic renal failure was prescribed doxazosin 8mg twice daily. One dose of 4mg was given.	1	Dose 2.1	A	Interpretation or selection error.
MC	22 Mar	6 am	A patient with chronic renal failure was prescribed Calcichew (calcium carbonate 1.25g), one tablet three times daily, as a phosphate binding agent. One dose of sodium bicarbonate 500mg was instead given.	1	Drug * 1.6	A Rx	Interpretation or selection error. The medication order was written as 'calcium carbonate' instead of 'Calcichew'.

MC	24 Mar	6 am	A patient with chronic renal failure was given an unordered dose of amlodipine 5mg.	1	Unordered 3.9	A	The patient had been taking amlodipine prior to her admission, and, noticing that there was none in her tablet cup, asked the nurse what had happened to it. The nurse gave her a dose of amlodipine 5mg without checking the drug chart. The patient in the next bed was prescribed amlodipine 5mg daily and the nurse may have confused the two patients.
PA	16 Mar	noon	An immunosuppressed renal transplant patient was prescribed mycystatin oral suspension 1ml four times daily for the treatment of an oral <i>Candida</i> infection. The first dose was omitted.	1	Omission 0.8	S	This newly prescribed medication was not yet available on the ward.
PE	19 Mar	noon	A patient with chronic renal failure and hypertension was prescribed lisinopril 2.5mg daily. The first dose was omitted.	1	Omission 2.6	S	This newly prescribed medication was not yet available on the ward.
QU	16 Mar	6 am	A patient with Crohn's disease had been taking enteric coated prednisolone 30mg once daily. One dose of the plain uncoated tablets was given.	1	Form 0.8	S	This newly prescribed medication was not yet available on the ward, and the nurse gave the patient some of the uncoated tablets instead..
QU	16 Mar	6 pm	A patient with Crohn's disease had been taking enteric coated prednisolone 30mg daily. This dose was reduced to 20mg. On the day of the reduction he received a total dose of 50mg.	1	Extra 2.1	A Rx	The patient had already received a dose of 30mg at 6 am when the medication order was rewritten. At 6 pm the nurse saw the new medication order and administered an extra dose of 20mg.
QU	20 Mar	6 am	A patient with mouth ulcers was prescribed chlorhexidine mouth wash 10ml four times daily. The first dose was omitted.	1	Omission 1.3	S	This newly prescribed medication was not yet available on the ward.
SH	16 Mar 17 Mar 18 Mar	6 am 6 pm 6 am	A patient with chronic renal failure was prescribed Calcichew (calcium carbonate 1.25g), two tablet three times daily, as a phosphate binding agent. Three doses of only one tablet were given during a three day period.	3	Dose 3.4	A	Interpretation or selection error.
SH	17 Mar	6 am	A patient with dyspepsia was prescribed lansoprazole 15 mg once daily. The first dose was omitted.	1	Omission 1.1	S	This newly prescribed medication was not yet available on the ward.
TH	19 Mar	6 am	A patient was taking enteric coated prednisolone 20mg once daily. One dose of the uncoated plain tablets was given.	1	Form 1.3	A	Interpretation or selection error.

a: Gavison and lactulose wrong dose errors are excluded. b: Dates refer to 1998; 18th March was a Monday.

c: MAEs = medication administration errors; figures refer to the number of MAEs that occurred

d: 'Drug' = wrong drug; 'Dose' = wrong dose; 'Extra' = extra dose; 'Form' = wrong form; 'Unordered' = unordered drug.

e: * = observer intervened to prevent the error; ** = patient prevented the error.

f: Stage of the drug distribution system in which the MAEs originated. 'A' = administration; 'S' = supply; 'Rx' = ambiguous or unclear prescription that contributed to the error.

g. Information used to score the severity of the event.

Medical ward, patients' own drugs system ^a

Patient	Date ^b	Time	Events observed ^e	No of MAEs ^c	Type ^{d,e} & severity score	Stage ^f	Additional information, likely causes and contributing factors.
AM	03 June	6 pm	A patient with chronic renal failure and hypertension was prescribed enalapril 2.5mg twice daily. The second dose was omitted.	1	Omission 2.6	A	The nurse apparently did not see that this dose was due.
AM	06 June	noon	A patient with chronic renal failure suffering from nausea and vomiting was taking oral cyclizine 50mg three times daily. One dose was omitted.	1	Omission 1.9	A	The nurse did not see the relevant medication order; the order was written on the second page of the drug chart which the nurse did not examine.
AM	06 June	6 pm	A patient with chronic renal failure suffering from nausea and vomiting was taking oral cyclizine 50mg three times daily. Having already missed the previous dose, the patient missed another dose.	1	Omission 3.1	A	The nurse saw an empty bottle of cyclizine in the patient's box and assumed that the supply had been exhausted. However another full bottle had been dispensed and was in the box.
AM	06 June	6 pm	A patient with chronic renal failure, nausea and vomiting and hypokalaemia was prescribed Sando K tablets (12 mmol potassium) at a dose of two tablets three times daily. The first dose was omitted.	2	Omission 2.9	A	The nurse apparently did not see that this medication order was due.
AM	07 June	6 pm	A patient with chronic renal failure, nausea and vomiting and hypokalaemia was prescribed Sando K tablets (12 mmol potassium) at a dose of two tablets three times daily. On the second day of this course, one dose of only one tablet was given.	1	Dose 1.6	A	Interpretation or selection error.
AM	10 June	6 pm	A patient with chronic renal failure was prescribed lansoprazole 15mg twice daily for the treatment of dyspepsia. One dose of 30mg was instead given.	1	Dose ** 1.3	A	Interpretation or selection error.
BA	01 June 02 June 03 June 04 June	6 am 6 am 6 am 6 am	A patient suffering from anxiety was prescribed diazepam 2.5mg once daily. On four consecutive mornings he was given a dose of 4mg.	4	Dose 1.6	A <i>Rx</i>	Interpretation error; the nurses apparently thought that the order said '2.5mg' instead of '2.5mg'.

BA	06 June	noon	A patient prescribed allopurinol 200mg daily for the treatment of hyperuricaemia and urate stones was also prescribed colchicine 500mcg three times daily for the prophylaxis of gout attacks. After one week, the patient was suffering from nausea and the dose of colchicine reduced to 500mcg twice daily at 6 am and 6 pm. Three days after this reduction, the patient received an extra dose of 500mcg at noon.	1	Extra 2.3	A Rx	The medication order was altered by crossing through the circled '12' on the drug chart, leaving '6' and '18' circled. The nurse looked only at the administration part of the chart, and seeing that doses had previously been given at noon, apparently assumed that this medication order was still active for noon
BA	07 June	10pm	A patient with a previous renal transplant was prescribed tacrolimus 1mg twice daily. One dose was omitted.	1	Omission * 2.9	A	The nurse apparently did not see that this medication order was due.
BE	03 June	noon	An immunosuppressed patient with a previous renal transplant was prescribed amphotericin mouthwash 1ml four times daily, for the treatment of an oral <i>Candida</i> infection. The first dose was omitted.	1	Omission 0.8	S	This newly prescribed medication was not yet available on the ward.
BE	06 June 08 June	noon 6 pm	An immunosuppressed patient with a previous renal transplant was prescribed amphotericin mouthwash 1ml four times daily, for the treatment of an oral <i>Candida</i> infection. Two doses were omitted, one on the third day of the course and one on the fifth.	2	Omission 1.9	A	The nurse looked unsuccessfully in the drug trolley for this medication, which was at the patient's bedside.
BI	02 June	6 am	A patient with chronic renal failure and a chest infection was prescribed amoxycillin 500mg three times daily. On the third day of the course, one dose of only 250mg was given.	1	Dose 2.6	A	Interpretation or selection error.
DO	06 June	6 pm	A patient with atrial fibrillation was prescribed daily warfarin for the prophylaxis of deep vein thrombosis. The dose was adjusted daily according to his INR. On this day, his INR was only 1.1 and a dose of 10mg therefore prescribed. This dose was omitted.	1	Omission 3.9	A	The nurse apparently did not see that the dose of warfarin had been prescribed, and omitted the dose.
FU	04 June	6 am	A patient was taking sotalol 80mg twice daily for the prophylaxis of cardiac arrhythmias. One dose was omitted.	1	Omission * 3.4	A	The nurse opened the wrong patient's box and, since she could not find any sotalol, assumed that it was not available.
GP	05 June	6 am	A man admitted for the donation of a kidney to his son was prescribed vitamin tablets BPC, one daily. The first dose was omitted.	1	Omission 0.3	S	This newly prescribed medication was not yet available on the ward.

GP	05 June	6 am	A man admitted for the donation of a kidney to his son was prescribed thiamine 50mg once daily. The first dose was omitted.	1	Omission 0.3	S	This newly prescribed medication was not yet available on the ward.
HA	05 June 05 June 06 June 06 June	6 pm 10 pm 6 am noon	A patient with an ulcerated tongue was prescribed Diffiam (benzylamine hydrochloride) mouthwash, 10ml four times daily. The first four doses were omitted.	4	Omission 3.1	S	This newly prescribed medication was not yet available on the ward.
HA	08 June	6 am	A patient with chronic renal failure was prescribed Titrilac (calcium carbonate 420mg and glycine 180mg), two tablets three times daily, as a phosphate binding agent. A dose of only one tablet was given	1	Dose 1.3	A	Interpretation or selection error.
LA	06 June	10 pm	A patient with asthma, admitted for a surgical procedure, was prescribed nebulised ipratropium bromide 500mcg four times daily. A dose of only 250mcg was given.	1	Dose 1.4	A	Interpretation or selection error.
McC	01 June	6 pm	A patient with chronic renal failure and constipation was taking senna, two tablets daily. A dose was omitted.	1	Omission 1.4	A	The nurse apparently did not see that this medication order was due.
McC	09 June	6 am	A patient with chronic renal failure and gastro-oesophageal reflux was prescribed lansoprazole 30mg daily. One dose was omitted.	1	Omission 1.6	S	The supply previously dispensed for this patient had been depleted.
McK	06 June	6 am	A patient with chronic renal failure and hypertension was prescribed nifedipine LA 30mg once daily. One dose of three nifedipine SR 10mg tablets was given.	1	Form 2.6	A	Interpretation or selection error.
PI	07 June	10 pm	A patient suffering from arrhythmias post cardiac surgery was prescribed amiodarone 200mg three times daily as a loading dose. On the fifth day of this regime, a dose was omitted.	1	Omission 1.9	S	The patient had been transferred from a cardiac ward to the renal ward, where no amiodarone was available.
PI	08 June	6 am	A patient suffering from arrhythmias post cardiac surgery (controlled with amiodarone) and acute renal failure received an unordered dose of digoxin 62.5mcg in addition to his prescribed medication.	1	Unordered * 3.3	A	Another patient's drug chart was at the end of this patient's bed. He was given the drugs ordered on this chart. Later, when the nurse realised what had happened, he was also given the medication prescribed on his own drug chart.
PI	08 June	6 am	A patient suffering from arrhythmias post cardiac surgery (controlled with amiodarone) and acute renal failure received an unordered dose of ferrous sulphate 200mg in addition to his prescribed medication.	1	Unordered * 0.6	A	Another patient's drug chart was at the end of this patient's bed. He was given the drugs ordered on this chart. Later, when the nurse realised what had happened, he was also given the medication prescribed on his own drug chart.

SP	05 June	6 am	An immunosuppressed patient with a previous renal transplant was prescribed amphotericin mouthwash 1ml four times daily, for the treatment of an oral <i>Candida</i> infection. The first dose was omitted.	1	Omission 1.5	S	This newly prescribed medication was not yet available on the ward.
SP	06 June	6 am	An immunosuppressed patient with a previous renal transplant was prescribed amphotericin mouthwash 1ml four times daily, for the treatment of an oral <i>Candida</i> infection. Having already missed the first dose, the patient missed the second dose scheduled.	1	Omission 1.9	A	The nurse assumed that the patient had been given a supply of the medication and was self-administering it, and signed the drug chart accordingly. However although the medication was available on the ward, it had not yet been given to the patient.
SP	07 June	10 pm	A patient with a previous renal transplant was prescribed tacrolimus 8mg twice daily. One dose of 6mg was given.	1	Dose * 3.6	A	Interpretation or selection error.
ST	04 June	6 am	A patient with a previous renal transplant was prescribed alfalcidol 0.5mcg daily. One dose of 0.25mcg was given.	1	Dose 1.0	A	Interpretation or selection error.
SW	01 June	noon	A patient with hypokalaemia was prescribed four tablets of Slow K (8mmol potassium in a slow-release formulation), three times a day. One dose of two tablets of Sando K (12 mmol potassium in an effervescent tablet) was instead given.	1	Dose * 0.3	A Rx	The dose was prescribed as 'IIII tablets', which the nurse could not interpret. Since two tablets was the dose with which he was most familiar, he decided to give two tablets and selected the Sando K. Following the researcher's intervention, it was apparent that he did not know that Slow K and Sando K were different products.
SW	02 June	noon	A patient with an infected CAPD catheter site was prescribed oral flucloxacillin 500mg four times a day and penicillin V 500mg four times a day. The first dose of penicillin V was omitted.	1	Omission 0.9	S	This newly prescribed medication was not yet available on the ward.
WE	06 June	6 pm	A patient was prescribed warfarin 5mg daily for the prophylaxis of deep vein thrombosis. One dose was omitted.	1	Omission 2.6	A Rx	At 6 pm the doctor had not yet indicated the dose of warfarin to be administered and no dose was given. By 10 pm a dose of 5mg had been prescribed, but the nurse was not willing to administer this dose in case it had been given at 6 pm but not signed for.

WE	08 June	noon	A patient with a previous renal transplant was prescribed alfacalcidol 2mcg daily. One dose was omitted.	1	Omission 1.3	S	This newly prescribed medication was not yet available on the ward. The 0.25mcg capsules were available, but the nurse did not want to give the patient eight of these.
WE	10 June	6 pm	A patient with a previous renal transplant was prescribed alfacalcidol 2mcg daily. One dose of 0.25mcg was given.	1	Dose 1.6 *	A	Interpretation error. Following the observer's intervention, it was apparent that the nurse was unaware that this medication was prescribed in more than one dose.

Footnotes:

- a: Gavison and lactulose wrong dose errors are excluded.
- b: Dates refer to 1998; 1st June was a Monday.
- c: MAEs = medication administration errors; figures refer to the number of MAEs that occurred
- d: 'Drug' = wrong drug; 'Dose' = wrong dose; 'Extra' = extra dose; 'Form' = wrong form; 'Unordered' = unordered drug.
- e: * = observer intervened to prevent the error; ** = patient prevented the error.
- f: Stage of the drug distribution system in which the MAEs originated. 'A' = administration; 'S' = supply; 'Rx' = ambiguous or unclear prescription that apparently contributed to the error.
- g. Information used to score the severity of the event.

Appendix 17

**Description of some events that were not considered
medication administration errors**

Appendix Seventeen: Events of interest that were not considered medication administration errors

The following tables give details of doses that were not included as MAEs but nevertheless may be of interest. In many of these cases the researcher was not certain of the medication intended by the prescriber or whether an error had occurred; these doses were not included as opportunities for error. In other cases no error occurred according to the definitions used in the present study, but the doses concerned may have been classified as errors according to the definitions used by other authors.

Surgical ward - traditional ward pharmacy system

Date *	Time	Patient	Events observed	OE?†	Doses
12 -19 Jan	Each 6 am & 6 pm round	WH	This patient was prescribed diclofenac 75mg twice daily. Diclofenac SR had been dispensed and was administered during all observed rounds. The observer attempted to find out whether the plain formulation or the SR formulation was intended, but the patient's medical notes referred only to diclofenac. The SR formulation is usually given twice daily; however the researcher could not be certain which formulation was intended and these doses therefore excluded as opportunities for error.	No	14
12 Jan 13 Jan 14 Jan 15 Jan 16 Jan	6 am 6 am 6 am 6 am 6 am	WH	Prednisolone 20mg once daily was prescribed. During five of the six 6 am rounds observed, the patient stated that she usually took the enteric coated preparation. The nurses therefore administered the enteric coated tablets. The researcher was not certain of the preparation intended, and these doses therefore excluded as opportunities for error.	No	5
18 Jan	6 am	WH	Prednisolone 20mg once daily was prescribed. During five of the six 6 am rounds observed, the patient stated that she usually took the enteric coated preparation. However, on this morning the patient did not request the enteric coated preparation and the plain uncoated tablets given. The researcher was not certain of the preparation intended, and these doses therefore excluded as opportunities for error.	No	1
12 Jan 13 Jan 14 Jan 15 Jan 16 Jan 18 Jan 19 Jan	6 am 6 am 6 am 6 am 6 am 6 am 6 am	GR	Prednisolone 20mg once daily was prescribed. During each 6 am rounds observed, the patient stated that he usually took the enteric coated preparation. The nurses therefore administered the enteric coated tablets. The researcher was not certain of the preparation intended, and these doses therefore excluded as opportunities for error.	No	7
12 Jan 12 Jan 12 Jan 13 Jan 14 Jan 15 Jan 17 Jan 18 Jan	6 am noon 6 pm noon 6 pm noon 6 pm 10 pm	HAS	An elderly post-operative patient was prescribed soluble paracetamol 1g four times daily. On eight occasions she was given regular paracetamol tablets, which she swallowed easily. These doses were therefore not considered to be MAEs.	Yes	8
13 Jan 13 Jan 14 Jan	6 am 6 pm 6 am	SM	The patient was prescribed venlafaxine 70mg twice daily. The capsules are supplied in multiples of 75mg, and she was administered 75mg on each occasion. The researcher was not certain of the prescriber's intentions and these doses therefore excluded.	No	3
14 Jan	6 pm	CO	A patient was prescribed propranolol 80mg once daily. He was given an 80mg Inderal LA capsule from his own supply. The researcher was not certain of the prescriber's intentions and this doses therefore excluded.	No	1

15 Jan	noon	WH	This patient was prescribed one tablet of SandoCal 400 at 6 am and one at 6 pm. On 15 Jan, the researcher saw that the patient was given a dose at 6 am; however she did not take the dose immediately and left it at her bedside. At noon, the patient asked the nurse where her 6 am dose of SandoCal was, as she was certain that she had not taken it. The nurse therefore gave her another tablet. The researcher did not know whether or not the patient had taken the 6 am dose and the noon dose was therefore excluded as an opportunity for error.	No	1
17 Jan 18 Jan	10 pm 6 am	WH	This patient had been prescribed 'Serc 16 - one tablet' (betahistine 16mg) three times daily, on her previous drug chart. As the 8mg tablets were the only formulation available in the hospital, these had been dispensed; the pharmacist had indicated that two of the 8mg tablets should be given. When the chart was rewritten, the doctor transcribed the order as 'Serc 16 - two tablets'. However, the patient was given two of the 8mg tablets, as on the previous drug chart. The doses given therefore deviated from the medication order as prescribed. However, the prescription, rather than the doses administered, was incorrect. These doses were therefore not included as opportunities for error.	No	2
18 Jan 19 Jan	10 pm 6 am	NA	This patient was prescribed nifedipine 10mg twice daily. For both doses observed, he was given 10mg nifedipine SR tablets. According to the patient's medical notes, he was previously taking the SR tablets and these doses therefore not considered opportunities for error.	No	2
19 Jan	6 am	WH	During the last observed round, the prednisolone, clonidine and medroxyprogesterone prescribed for this patient were unavailable and therefore omitted. The observer did not know whether the doses were given later and the doses therefore excluded as opportunities for error.	No	3
Many	Many	Many	Many patients were prescribed diltiazem twice daily. In every case, diltiazem SR was administered. This is the only diltiazem product in the study hospital's formulary, and it is the appropriate product for twice daily administration. It was therefore assumed that this was the product intended.	Yes	Many

* dates refer to 1998

† OE: opportunity for error; 'yes' indicates that the doses concerned were included as opportunities for error; 'no' indicates that they were excluded.

Surgical ward - PODS system

Date *	Time	Patient	Events observed	OE? †	Doses
2 Apr	noon	CA	This patient was prescribed isosorbide mononitrate, frusemide and ranitidine. On this occasion, she was unable to swallow tablets and a dose of each drug was therefore omitted. This was considered to be an omission for a clinical reason; the doses were therefore not included as errors nor opportunities for error.	No	3
3 Apr 4 Apr 5 Apr 6 Apr 7 Apr 8 Apr	6 am 6 am 6 am 6 am 6 am 6 am	IP	A patient was prescribed two Forceval capsules daily (multi-vitamins and minerals), which she had been taking prior to her admission. This preparation is not in the hospital formulary and the patient had therefore been prescribed vitamins capsules BPC, two daily, for the duration of her hospital stay. However the Forceval medication order had not been discontinued and the corresponding section of the drug chart endorsed 'out of stock' each day. These doses were not considered errors nor opportunities for error.	No	6
3 Apr	6 am	HAS	A newly admitted patient had been prescribed prednisolone 20mg once daily. On April 3rd, the patient stated that she always took the enteric preparation. The nurse therefore administered the enteric coated preparation instead of the plain tablets. The prescription was later endorsed by the pharmacist as being for the enteric coated preparation, which was given during the remainder of the observation period.	No	1
5 Apr 6 Apr 7 Apr	6 am 6 am 6 am	BE	A patient was prescribed nifedipine 10mg once daily. On each observed occasion he was given one tablet of nifedipine retard 10mg. The researcher was unable to determine whether the capsules or modified release tablets were intended, and these doses therefore excluded as opportunities for error.	No	3
6 Apr	noon	BE	A patient due doses of sertraline and metronidazole was unable to swallow tablets. The nurse therefore crushed a tablet of each preparation using scissors and a spoon. Some powdered medication may have been lost in the process, however the researcher was unable to determine whether or not a wrong dose error had occurred. These doses were therefore excluded as opportunities for error.	No	2
2 Apr	6 pm	SC	A patient was prescribed soluble paracetamol, 1g four times daily. She was given one dose of regular paracetamol tablets, which she swallowed easily.	No	1
7 Apr	noon	SI	A patient was prescribed cephadrine 500mg four times daily. The first dose was not given during the drug round as the doctor was using the drug chart to prescribe the patient's take-home medication. By the time of the next drug round, the patient had been discharged and the researcher therefore could not determine whether or not the dose was given later.	No	1
8 Apr	6 pm	ENN	A patient was prescribed slow release isosorbide mononitrate, 120mg once daily. When the nurse tried to administer this dose, the patient said that she only took 90mg daily. The nurse therefore omitted the dose and left the drug chart for the prescriber to check which dose was intended. The doctor later changed the dose to 120mg, but the 8 April dose was never given. This omission was considered to be for a clinical reason, and excluded as an opportunity for error.	No	1

8 Apr	noon	HAS	This patient was prescribed ranitidine 150mg twice daily at 6 am and 6 pm. At noon, the nurse started to prepare an extra dose of ranitidine for this patient. However, this nurse had made a similar error with the previous patient, where the patient had consumed the dose before either the nurse or the observer realised that an error had occurred. The nurse, who was carrying out his first drug round unaccompanied by another nurse, was very upset at having made an error. In the case of Ms HAS, the researcher intervened immediately to prevent the dose of ranitidine being prepared, so as to avoid having to intervene later and further distress the nurse. This dose was excluded as an opportunity for error as the researcher's intervention was not timed so as to give the nurse every opportunity to prevent the error.	No	1
7 Apr	noon	IP	A patient was prescribed paracetamol, two tablets when required. One dose of two co-dydramol tablets was instead given. This dose was not an opportunity for error as it did not involve medication prescribed to be administered regularly.	No	1
Many	Many	Many	Many patients were prescribed diltiazem twice daily. In every case, diltiazem SR was administered. This is the only diltiazem product in the study hospital's formulary, and it is the appropriate product for twice daily administration. It was therefore assumed that this was the product intended.	Yes	Many

* dates refer to 1998

† OE: opportunity for error; 'yes' indicates that the doses concerned were included as opportunities for error; 'no' indicates that they were excluded.

Medical ward - traditional ward pharmacy system - phase 1

Date *	Time	Patient	Events observed	OE? †	Doses
26 Jan	noon	HU	This patient was prescribed 'Augmentin 250', one tablet three times a day. The nurse could only find the 625mg tablets, and therefore asked the doctor to change the prescription to 625mg. The doctor changed the prescription accordingly, and the 625mg tablets therefore given.	Yes	1
28 Jan 29 Jan	6 am 6 am	SU	'Prednisolone 7.5mg' was prescribed to be given once daily. The patient said that she usually took the enteric coated preparation, and had her own supply of the 2.5mg tablets. During the two drug rounds observed, the nurse gave one plain 5mg tablet and one of the patient's own 2.5mg enteric coated tablet. These doses were excluded as opportunities for error as it was not clear what the prescriber intended.	No	2
29 Jan 4 Feb	6 am 6 am	SHA	This patient was prescribed 'codeine phosphate 60mg' once daily for the treatment of diarrhoea. On two occasions, the nurse chose to give only 30mg as the patient's diarrhoea was improving, and endorsed the drug chart accordingly	No	2
26 Jan	6 am	SHE	This newly admitted patient was prescribed 'verapamil SR 240mg' once daily at 8 am. None was available on the ward during the 6 am drug round. The patient was discharged before the noon round and the observer therefore could not determine whether the patient subsequently received the dose.	No	1
31 Jan	10 pm	SHA	'GTN Spray x 1' (glyceryl trinitrate, 400 mcg per metered dose) was prescribed to be given when required. The patient was instead given one sublingual glyceryl trinitrate 500 mcg tablet. This dose was excluded as an opportunity for error as the medication concerned was prescribed to be given 'when required'.	No	1
1 Feb	6 am	NI	The patient was prescribed 'Augmentin 1 tablet' to be given three times a day. The nurse did not give the dose as she wanted to clarify with the prescriber the dose intended. The patient was discharged before the noon round and the observer was therefore unable to determine if this dose was subsequently given.	No	1
1 Feb	6 pm	ME	This patient was prescribed a dose of doxazosin 6mg. Only the 4mg tablets were available on the ward, and a dose was therefore prepared by cutting one of the unscored 4mg tablets into halves with scissors. The observer judged that about 6mg had been given and this dose therefore included as an opportunity for error but not as an MAE.	Yes	1
1 Feb	6 pm	VA	A dose of 25mg metoprolol was prescribed. Only 50mg tablets were available, and the nurse therefore prepared the dose by cutting one of these in half with a pair of scissors. The observer judged that about 25mg had been given and this dose therefore included as an opportunity for error but not as an MAE.	Yes	1
2 Feb 3 Feb	6 am 6 am	ME	A dose of 25mg lamotrigine was prescribed to be given once daily. Only 50mg tablets were available, and on two occasions the nurse therefore prepared the dose by cutting one of these in half with a pair of scissors. The observer judged that about 25mg had been given and these doses were therefore included as an opportunities for error but not MAEs.	Yes	2

2 Feb	6 am	ME	This patient was prescribed 'sodium valproate 600mg' twice daily. During each observed round, the enteric coated tablets were given. The researcher was not certain of the preparation intended, and these doses therefore excluded as opportunities for error.	No	6
2 Feb	6 pm				
3 Feb	6 am				
3 Feb	6 pm				
4 Feb	6 am				
4 Feb	6 pm				
2 Feb	noon	WH	Nystatin oral suspension, 1ml four times daily was prescribed. On this occasion the patient self-administered the dose gave himself 2ml.	No	1
4 Feb	6 am	DU	A patient was prescribed 'nifedipine 30mg' once daily. One tablet of the patient's own XL preparation was given. The researcher was certain that this was the preparation intended and the dose therefore included as an opportunity for error but not as an MAE.	Yes	1
4 Feb	6 am	DU	This patient was prescribed 'spironolactone 500mg' once daily. She had a supply of her own 25mg tablets and the nurse gave two of these. The researcher was not certain of the prescriber's intention and the dose excluded as an opportunity for error.	No	1
4 Feb	10 pm	HI	This patient had been prescribed penicillin V 500mg four times daily. None was available on the ward during the last observed round, and the researcher was unable to ascertain whether the dose was subsequently given.	No	1
Many	Many	Many	On many occasions, doses were apparently omitted while patients were receiving dialysis.	No	Many

* dates refer to 1998

† OE: opportunity for error; 'yes' indicates that the doses concerned were included as opportunities for error; 'no' indicates that they were excluded.

Medical ward - traditional ward pharmacy system - phase 2

Date *	Time	Patient	Events observed	OE? †	Doses
16 Mar	6 am noon	DE	This patient was prescribed 'Slow Phosphate', two tablets three times daily. He had been dispensed Phosphate Sandoz (effervescent tablets containing 16.1 mmol phosphate), and these were administered for each observed dose. Slow Phosphate does not exist; the researcher was therefore not certain what had been intended by the prescriber and excluded these doses as opportunities for error.	No	2
17 Mar	noon	McK	A patient had been prescribed Neprovite (multivitamin) tablets, one three times daily. The nurse omitted the lunchtime dose as she was aware that this drug was usually given only one daily. The doctor subsequently changed the prescription to once only and this omission therefore excluded as an opportunity for error.	No	1
20 Mar	10 pm	MA	This patient had been prescribed 'Fragmin' (dalteparin), 2500 units once daily. The nurse instead prepared a dose of heparin sodium 2500 units. The researcher intervened. This dose was not included as an opportunity for error as it involved a parenteral dose.	No	1
21 Mar	6 am	PE	Indipamide 1.5mg was prescribed to be given once daily at 6 am. None was available during the 6 am drug round. By 6 pm the medication order had been discontinued, and the omitted dose therefore excluded as an error and as an opportunity for error.	No	1
21 Mar	6 am	WA	The patient was given a dose of 5ml simple linctus for which no prescription existed. A medication order was later written by the doctor on the 'when required' side of the drug chart. This dose was excluded as an opportunity for error as a 'when required' drug was involved.	No	1
Many	Many	Many	On many occasions, doses were apparently omitted while patients were receiving dialysis.	No	Many

* dates refer to 1998

† OE: opportunity for error; 'yes' indicates that the doses concerned were included as opportunities for error; 'no' indicates that they were excluded.

Medical ward - PODs system

Date *	Time	Patient	Events observed	OE? †	Doses
1 June	6 pm	AM	Frusemide 120mg was prescribed to be given once only at 6pm on 2 June, but a dose was prepared on 1 June. The observer intervened to prevent the error from occurring. This event concerned a dose prescribed to be given 'once only' and was therefore not included as an opportunity for error.	No	1
2 June	10 pm	RO	This patient had her own quinine tablets in a pillbox, and took a dose herself. Quinine was not prescribed on her drug chart. However, a medication order for quinine was written the following day and this dose considered neither an error nor an opportunity for error..	No	1
4 June	6 am	ST	This patient was designated 'nil by mouth' prior to surgery and was given a dose of ferrous sulphate 200mg while doses of lansoprazole and losartan were omitted. The ferrous sulphate was considered an opportunity for error but the lansoprazole and losartan were not.	No	2
4 June	6 am	GP	This patient was given a dose of two senna tablets, although no medication order existed for this drug. A medication order for senna, two tablets when required, was subsequently written by the doctor.	No	1
5 June 7 June 8 June 9 June 10 June	6 am 6 am 6 am 6 am 6 am	SP	'Nifedipine SR 90mg' was prescribed to be given once daily. During each observed round, the patient was given one tablet of nifedipine LA 90mg. The researcher was certain that this was the medication intended and these doses therefore included as opportunities for error but not as MAEs.	Yes	5
5 June	6 pm	BA	'Augmentin 625mg' (co-amoxiclav) was prescribed to be given three times daily. The nurse apparently saw the 'clavulanic acid 125mg' on the bottle of co-amoxiclav and assumed that six tablets were to be given. She queried this with the doctor, who explained that each tablet was 625mg of co-amoxiclav and the correct dose therefore given.	Yes	1
5 June 6 June 6 June 6 June 7 June 7 June	6 pm 6 am noon 10 pm 6 am noon	HA	This patient was prescribed 'Atrovent 5mg'(ipratropium bromide) four times a day. On the six occasions observed, the patient was instead given 500 mcg. The usual dose of this medication is 250 - 500 mcg four times daily; these doses were excluded as opportunities for error as it was considered likely that a prescribing error had occurred.	No	6
6 June	6 am	BA	This patient had been prescribed diazepam 2mg once daily at 6 am and, on a separate medication order. 2mg three times daily. On the occasion observed he was given two doses, each of 2mg. The researcher was not certain of the prescriber's intention and the extra dose therefore considered neither an MAE nor an opportunity for error.	No	1
7 June	10 pm	SP	This patient was given a dose of lactulose 10ml, for which no medication order existed. A medication order for lactulose, 10ml when required, was written the following day and this dose considered neither an error nor an opportunity for error.	No	1
7 June	10 pm	GP	This patient was given a dose of lactulose 10ml, for which no medication order existed. A medication order for lactulose, 10ml when required, was written the following day and this dose considered neither an error nor an opportunity for error.	No	1

8 June	6 am	WE	'Prednisolone 30mg' was prescribed to be given once daily. The patient's own supply of the enteric coated preparation was used to administer the dose. The researcher could not be certain of the medication intended by the prescriber and this dose therefore excluded as an opportunity for error.	No	1
9 June	6 am	HA	This patient had been prescribed ferrous gluconate, but no dose or time of administration had been indicated on the drug chart. The nurse gave one dose of 300mg during the 6 am drug round, as on the patient's previous drug chart.	No	1
9 June	6 am	SM	Omeprazole 20mg had been prescribed to be given once daily at 8 am. None was available on the ward during the 6 am drug round. The patient had been discharged by the time of the 6 pm drug round, and the researcher was therefore unable to determine whether or not the dose was subsequently given.	No	1
9 June	6 am	CA	Carbimazole 30mg had been prescribed to be given once daily at 8 am. None was available on the ward during the 6 am drug round. The patient had been discharged by the time of the 6 pm drug round, and the researcher was therefore unable to determine whether or not the dose was subsequently given.	No	1
Many	Many	Many	On many occasions, doses were apparently omitted while patients were receiving dialysis.	No	Many

* dates refer to 1998

† OE: opportunity for error; 'yes' indicates that the doses concerned were included as opportunities for error; 'no' indicates that they were excluded.

Appendix 18

Results of a logistic regression analysis of the unavailability-related medication administration errors

Appendix Eighteen: Results of a logistic regression analysis of the unavailability-related MAEs

The following table shows the detailed results of the multivariate logistic regression analysis carried out for the U-MAEs. The dependent variable was the probability of an error occurring; all independent variables were assumed to be categorical and in each case the reference category was the first one listed.

Variable	p value	Odds Ratio (95% confidence interval)
Observer	0.80	
<i>Observer 2</i>	<i>0.80</i>	<i>1.06 (0.69 - 1.60)</i>
Ward	0.07	
<i>Medical</i>	<i>0.07</i>	<i>0.68 (0.45 - 1.03)</i>
System	0.73	
<i>PODs system</i>	<i>0.73</i>	<i>1.07 (0.71 - 1.63)</i>
Day	0.02	
<i>Tuesday</i>	<i>0.63</i>	<i>1.20 (0.57 - 2.51)</i>
<i>Wednesday</i>	<i>0.76</i>	<i>1.13 (0.53 - 2.38)</i>
<i>Thursday</i>	<i>0.72</i>	<i>0.85 (0.35 - 2.05)</i>
<i>Friday</i>	<i>0.01</i>	<i>2.42 (1.24 - 4.73)</i>
<i>Saturday</i>	<i>0.82</i>	<i>1.10 (0.49 - 2.47)</i>
<i>Sunday</i>	<i>0.48</i>	<i>0.73 (0.30 - 1.75)</i>
Time	0.01	
<i>noon</i>	<i>0.001</i>	<i>2.35 (1.39 - 3.95)</i>
<i>6 pm</i>	<i>0.87</i>	<i>0.95 (0.52 - 1.74)</i>
<i>10 pm</i>	<i>0.62</i>	<i>1.16 (0.65 - 2.06)</i>
Constant	< 0.001	

Table A18.1 Results of the multivariate logistic regression analysis of the U- MAEs.

Appendix 19

Results of a logistic regression analysis of other types of medication administration error

Appendix Nineteen: Results of the logistic regression analysis for the O-MAEs

The following table shows the results of the multivariate logistic regression analysis carried out for the O-MAEs. The dependent variable was the probability of an O-MAE occurring; all independent variables were assumed to be categorical and in each case the reference category was the first one listed. The odds ratios for individual nurses are not shown; all had 95% confidence intervals that included zero.

Variable	p value	Odds Ratio (95% confidence interval)
Observer	0.24	
Observer 2	0.24	0.81 (0.57 - 1.15)
Ward	0.38	
Medical	0.38	0.36 (0.04 - 3.53)
System	0.30	
PODs system	0.30	0.81 (0.55 - 1.20)
Day	0.03	
Tuesday	0.76	1.10 (0.60 - 2.02)
Wednesday	0.63	0.86 (0.47 - 1.58)
Thursday	0.26	1.43 (0.77 - 2.65)
Friday	0.34	0.71 (0.35 - 1.43)
Saturday	0.10	1.64 (0.92 - 2.94)
Sunday	0.11	0.54 (0.26 - 1.15)
Time	0.61	
noon	0.25	1.59 (0.72 - 3.53)
6 pm	0.28	1.46 (0.74 - 2.88)
10 pm	0.39	1.23 (0.77 - 1.98)
Nurse	0.0001	
Constant	0.001	

Table A19.1 Results of the multivariate logistic regression analysis for the O-MAEs.

Appendix 20

Doses administered using patients' own drugs in the traditional ward pharmacy system

Appendix Twenty: Doses administered using patients' own drugs in the traditional ward pharmacy system

Ward	Patients' own drugs		Drugs dispensed for other patients	
	OE*	non-OE [†]	OE*	non-OE [†]
Surgical	15 (9) [‡]	17 (3)	22 (6)	0 (0)
Medical	19 (10)	64 (18)	37 (7)	1 (0)
TOTAL	34 (19)	81 (21)	59 (13)	1 (0)

Table A20.1 Doses administered using patients' own drugs and drugs dispensed for other patients during the traditional ward pharmacy system data collection periods.

* OE: Doses that were considered opportunities for error.

[†] non-OE: Doses that could not be observed in sufficient detail to be included as opportunities for error.

[‡] numbers in brackets refer to those doses that, in the observer's judgement, would otherwise have been U-MAEs.

Appendix 21

**Doses that were unavailable during the rounds for
which they were scheduled but given later**

Appendix Twenty-one: Doses that were unavailable during the drug rounds for which they were scheduled but given later

Ward	System	Number of doses given later
Surgical	Traditional ward pharmacy	2
Surgical	PODs	3
Medical	Traditional ward pharmacy	7
Medical	PODs	14

Table A21.1 Doses that were unavailable during the rounds for which they were scheduled but given later.

Appendix 22

Drug chart used at the study hospital

SURNAME		HOSPITAL NUMBER		WEIGHT	DRUG IDIOSYNCRASIES	
FIRST NAMES		SEX	DATE OF BIRTH	Sheet No.		
WARD		CONSULTANT		Start Date	MEDICAL GASES	End Date
WARD		CONSULTANT				
Start Date	DIET		End Date			
REGULAR PRESCRIPTIONS						
DATE AND MONTH →						
TICK TIMES OR ENTER VARIABLE DOSE →						
DRUG (APPROVED NAME)				6		
Dose	Route	Start Date	Valid Period	8		
				12		
Signature		Pharm.		14		
Additional Instructions				18		
				22		
DRUG (APPROVED NAME)				6		
Dose	Route	Start Date	Valid Period	8		
				12		
Signature		Pharm.		14		
Additional Instructions				18		
				22		
DRUG (APPROVED NAME)				6		
Dose	Route	Start Date	Valid Period	8		
				12		
Signature		Pharm.		14		
Additional Instructions				18		
				22		
DRUG (APPROVED NAME)				6		
Dose	Route	Start Date	Valid Period	8		
				12		
Signature		Pharm.		14		
Additional Instructions				18		
				22		
DRUG (APPROVED NAME)				6		
Dose	Route	Start Date	Valid Period	8		
				12		
Signature		Pharm.		14		
Additional Instructions				18		
				22		
DRUG (APPROVED NAME)				6		
Dose	Route	Start Date	Valid Period	8		
				12		
Signature		Pharm.		14		
Additional Instructions				18		
				22		

Appendix 23

List of publications

Appendix Twenty-three: List of publications

The following publications are based wholly or in part on the work described in this thesis:

Papers

Dean BS, Gallivan S, Barber ND and van Ackere A (1997). Mathematical modeling of pharmacy systems. *American Journal of Health-System Pharmacy* **54**, 2491-2499.

Dean BS, Kanabar PB, Ashby N, Taxis K and Barber N (1998). What can the drug chart tell us about medication administration? *The Hospital Pharmacist* **5**, 167-170.

Barber N and Dean BS (1998). The incidence of medication errors and how to prevent them. *Clinical Risk* **4**, 103-106.

Dean BS and Barber ND (1999). A validated, reliable method of scoring the severity of medication errors. *American Journal of Health-System Pharmacy* **56**, 57-62.

Dean BS, van Ackere A, Gallivan S and Barber ND (1999). The development of a simulation model of the hospital drug distribution system. *Health Care Management Science* **2**, 35-42..

Taxis K, Dean BS and Barber ND (1999). Hospital drug distribution systems in the UK and Germany - a study of medication errors. *Pharmacy World and Science* **21**, 25-31.

Dean BS (1999). Errors in medication administration (editorial). *Intensive Care Medicine* (in press).

Conference proceedings

Dean BS and Barber ND (1996). Do patients suffer from medication errors? - A systems approach. Abstract presented at the 9th International Social Pharmacy Workshop, Madison, USA. 11-14th August.

Dean BS (1996). Why do medication errors occur in your hospital? Workshop presented at the 25th European Symposium on Clinical Pharmacy, Lisbon, Portugal, 9-11th October.

Dean BS and Barber ND (1997). How much does it matter? - The development of a scale to measure the significance of medication errors. Abstract presented at the 3rd Health Services Research and Pharmacy Practice conference, London, 17-18th April.

Dean BS (1997). A comparison of three simulation packages in a hospital pharmacy management problem. Abstract presented at the Young OR conference, Guildford, 30th March - 1st April.

Dean BS, Barber ND, van Ackere A and Gallivan S (1998). The development of a simulation model of the hospital drug distribution system. Abstract presented at the 4th Health Services Research and Pharmacy Practice conference, Cardiff, 14-16th April.

Dean BS (1998). Medication errors and the hospital drug distribution system. Plenary lecture given at the XXVII Wissenschaftlicher Kongreß Bundesverband Deutscher Krankenhausapotheker [German Hospital Pharmacists' Association conference] Hannover, 14-17th May.

Dean BS and Barber ND (1998). A validated reliable method for scoring the severity of medication administration errors. Abstract presented at the British Pharmaceutical Conference, Eastbourne, 8-11th September.

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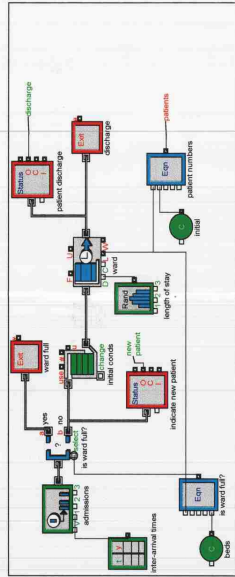
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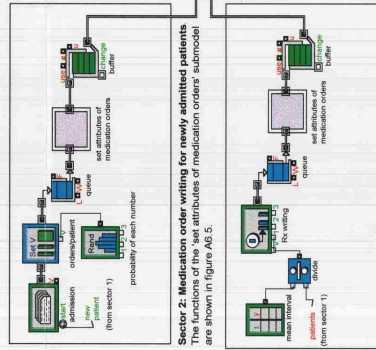
Executive



Random seed control



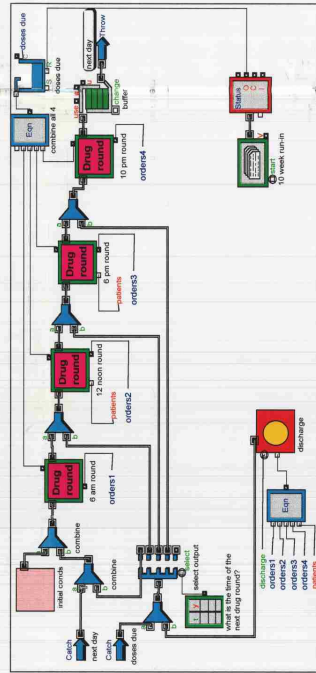
Sector 1: Patient admissions and discharges.



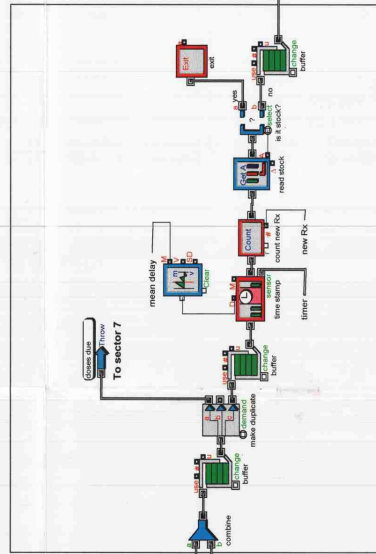
Sector 2: Medication order writing for newly admitted patients. The functions of the 'set attributes of medication orders' submodel are shown in figure A6.5.

Sector 3: Medication order writing for existing patients.

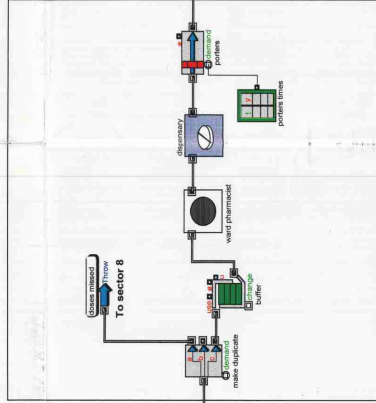
The functions of the 'set attributes of medication orders' submodel are shown in figure A6.5.



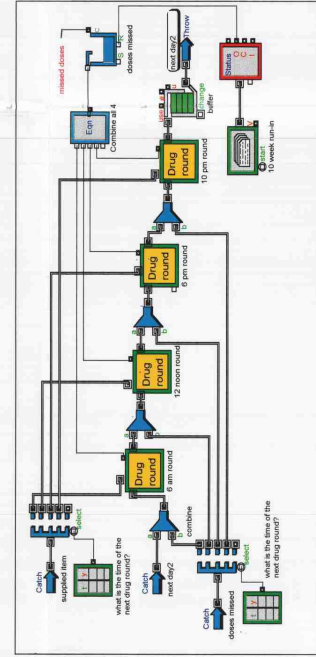
Sector 4: Determine whether item is available on ward. The functions of the 'doses due' submodel are shown in figure A6.5.



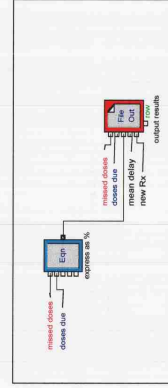
Sector 5: Delays in supply. The functions of the 'doses due' and 'doses due' submodels are illustrated in figures A6.9 and A6.10 respectively.



Sector 6: Return of dispensed items to the ward.



Sector 7: Calculate number of doses due. The functions of the 'doses due' submodel are shown in figure A6.13.



Sector 8: Calculate the omission rate.

On-screen appearance of the simulation model of the hospital drug distribution system.

A key to the symbols used is included in Appendix 6 of this thesis.

Title of thesis: Hospital medication administration errors - their simulation, observation and severity assessment.

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